S. Hrg. 98-1083 Pt. 2

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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## HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

SECOND SESSION

ON

**H.R. 6028/S. 2836**

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1985, AND FOR OTHER PURPOSES

**Part 2—(Pages 1-1233)**

**Department of Health and Human Services**
**Prospective Payment Assessment Commission**

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# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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TUESDAY, MARCH 27, 1984

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, D.C.*

The subcommittee met at 9 a.m., in room SR–428A, Russell Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, and Burdick.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### HEALTH RESOURCES AND SERVICES ADMINISTRATION

### STATEMENT OF ROBERT GRAHAM, ADMINISTRATOR

**ACCOMPANIED BY:**

- **ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS**
- **JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT**
- **EDWARD D. MARTIN, DIRECTOR, BUREAU OF HEALTH CARE DELIVERY AND ASSISTANCE**
- **THOMAS D. HATCH, DIRECTOR, BUREAU OF HEALTH PROFESSIONS**
- **DANIEL F. WHITESIDE, DIRECTOR, BUREAU OF HEALTH MAINTENANCE ORGANIZATIONS AND RESOURCES DEVELOPMENT**

#### PREPARED STATEMENT

Senator WEICKER. The hearing will come to order.

Today we will hear from the Health Resources and Services Administration, which supports a variety of programs, including health care services for underserved groups, health professions education and health planning, among other activities.

In fiscal 1984 the Congress provided $1.4 billion to this agency. However, the administration request for fiscal 1985 would make about an 81-percent cut in this funding level through program transfers and reductions and elimination of staff.

Here to defend the budget request is Dr. Robert Graham, Administrator of the agency.

I must confess, Dr. Graham, you face an unenviable task. We welcome you nevertheless. I am more than delighted to hear the explanation that accompanies the request.

Go right ahead.

[The statement follows:]

## STATEMENT OF ROBERT GRAHAM

Mr. Chairman and Members of the Committee:

I appreciate this opportunity to appear before you today to discuss the fiscal year 1985 budget request for the Health Resources and Services Administration. As you are aware, Mr. Chairman, this budget excludes the Indian Health Service, which is reviewed by the Department of the Interior and Related Agencies Subcommittee.

The Health Resources and Services appropriation consists of health services, health professions and nurse training, medical facilities and health maintenance organization programs. Authorizations for most of the agency's programs expire at the end of fiscal year 1984. The Administration is proposing legislation to extend authorizations for those programs for which funding is being requested in the FY 1985 budget.

The fiscal year 1985 budget request for Health Resources and Services is $271,919,000 and 2,419 positions. Included in this request are funds to continue the health care programs of the National Health Service Corps; the operation of the National Hansen's Disease Center; and to provide for the Federal payment to Hawaii for treatment of persons with Hansen's disease. Also included in this request are funds for the health professions and nurse training programs, and dollars to continue monitoring the medical facilities and health maintenance organization loan portfolios.

### Health Care Delivery and Assistance

The 1985 budget request of $67,174,000 for the National Health Service Corps will support a total field strength of 3,583 physicians and other health professionals, including 1,150 Federal salaried assignees. In addition to Federal salaried field assignees, 2,433 providers will be fulfilling their scholarship obligations as private practitioners, an increase of 495 over 1984. Through increased reliance on private placement with non-Federal employers and the private practice option, this budget will support an increase of 623 in total field strength while permitting a decrease in Federal funding. Under private placement or the private practice option, a person may complete the service obligation -- incurred while receiving a National Health Service Corps scholarship -- through private practice in a health manpower shortage area. A private practice assignment requires no Federal salary support and thus provides needed service at less expense to the government.

In 1985, 1,668 scholarship obligors will be available for service for the first time. Of these, 500 are estimated to elect the private practice option and 530 will elect to serve in private placement settings. About 638 will become Federal employees -- 438 with the National Health Service Corps and 200 with the Indian Health Service. An additional 50 scholarship obligors currently serving in the Corps are estimated to convert to private practice option (30) and the private placement (20).

The budget request includes $18,694,000 for the continuation of patient care, medical education and research activities at the National Hansen's Disease Center; for Hansen's Disease contract patient care; and for payments to survivors and dependents of the Tuskegee Syphilis Study. Also requested is $1,905,000 for payments to the State of Hawaii to partially support the cost and treatment of persons with Hansen's disease; and $20,793,000 to manage and operate these programs in the direct operations of the Bureau of Health Care Delivery and Assistance. Beginning in 1985, total costs for the Federal Employee Occupational Health program will be met on a reimbursable basis; therefore, no program funds are requested. The program will maintain the same level of activity as in 1984.

The total budget request for these health service programs is $108,566,000 and 1,781 positions.

## Health Professions

The 1985 request for health professions training activities is $99,983,000 for programs to improve the quality of health care available to Americans, and $15,305,000 and 253 positions for direct operations. The budget request also proposes an authorization of $175,000,000 for loan guarantees made under the Health Education Assistance Loan program.

Long term trends in health professions and nurse training activities have led to steadily increasing supplies of health professionals. At the same time, cumulative Federal contributions to health professions and nursing student assistance funds, including rapidly growing amounts of Health Education Assistance Loan guarantees, have put in place a foundation of Federal health professions student aid which will amount to more than $381 million in the 1984-85 academic year. Consequently, programs providing general support to health education designed to increase the numbers of practitioners are no longer an area of greatest need.

This budget request proposes to increase opportunities in health education for economically disadvantaged and minority persons; to increase the numbers of health care providers in underserved areas; and to support national priority special projects.

The Disadvantaged Assistance program is the principal direct program for increasing the numbers of underrepresented minorities and other disadvantaged individuals who are interested in pursuing a health career. The funding request of $24 million in 1985 will be used to involve the health professions schools in coordinating efforts to enlarge the minority applicant pool and to foster, among these schools, a commitment to increasing minority enrollments.

A major objective of the Area Health Education Centers program is to make institutionalized changes in traditional health professions education designed to better meet the needs of underserved areas through State and local health care initiatives.

The Health Professions Special Educational Initiatives program request of $3 million will continue support to enhance the delivery of health care in medically underserved areas and improve training in geriatrics and disease prevention.

Support of $4,188,000 for the Financial Distress program in 1985 will help preserve national resources for training minorities in health disciplines at four traditionally black health professions schools which have long been the principal educators of minority health practitioners.

In addition, the Administration is requesting $5,000,000 for a new program, Student Assistance for the Disadvantaged, which would provide additional student assistance resources for medical, dental, veterinary medicine, optometry, podiatry, and pharmacy students.

A major emphasis of the health professions programs is to fund national priority special projects. Programs which address these needs are Public Health Special Projects, parts of the Primary Care programs, Preventive Medicine Residencies, Advanced Nurse Training, and Nurse Practitioners. Public Health Special Projects will support programs that address issues of health promotion and illness prevention. Portions of the Primary Care program will continue to address the need to provide a sufficient supply of health professionals in this field trained in family medicine and the general internal medicine and pediatrics specialties. The Preventive Medicine residencies program will assist in increasing the number of needed preventive medicine specialists. Funding for Advanced Nurse Training and the Nurse Practitioners programs will continue projects of high priority addressed in the Institute of Medicine Study.

The request for direct operations will provide personnel and financial resources needed for effective "debt management" activities of the health professions and nursing student loan programs; conduct of the grants peer review process; and development of reports to the Congress.

## Health Maintenance Organizations and Resources Development

The budget request for the Health Maintenance Organizations and Resources Development programs is $40,035,000 and 231 positions.

In fiscal year 1985, direct operations funding of $12,335,000 will be used to: monitor approximately $1.2 Billion in outstanding health facility loans and loan guarantees in order to minimize Federal default liability; monitor health facility construction grants, recovering Federal funds where required; ensure that facilities which previously received Federal funding comply with requirements to provide a reasonable level of uncompensated care to persons unable to pay; monitor more than $150 million in outstanding Health Maintenance Organization loans and loan guarantees in order to minimize Federal default liability; encourage, through private sector financing, the continued growth and development of HMOs; evaluate HMOs to determine whether they meet all requirements for Federal qualification; evaluate competitive medical plans (CMPs) to determine their eligibility to contract with the Health Care Financing Administration to provide care for Medicare beneficiaries; monitor qualified HMOs, including those with Federal loans and loan guarantees, to assure continued compliance with all Federal regulatory requirements; and administer a program designed to promote energy conservation and cost savings by health facilities.

A total of $1,200,000 is requested to pay interest subsidies on guaranteed construction loans for four health professions teaching facilities. In addition, $26,500,000 is requested to pay interest subsidies on guaranteed loans made from the Medical Facilities Guarantee and Loan Fund. We also are requesting that a balance of $5,500,000 be transferred from the Direct Loan Account in this fund to provide the total amount of $32,000,000 required in FY 1985 for interest subsidy payments.

No funds are requested for the Health Planning programs, consistent with the Administration's intent to eliminate Federal regulatory involvement in State and local health planning activities. However, as we indicated in the budget request, if new legislation agreeable to the Administration is enacted, an appropriate budget request will be considered.

## Program Management

The Program Management request of $8,025,000 and 154 positions provides operational resources for the Office of the HRSA Administrator. This office provides leadership and support for a variety of agency-wide management and support functions including short and long-range program planning, evaluation, policy coordination, management of personnel, financial management, procurement, and management systems.

Thank you for providing me with the opportunity to summarize the Health Resources and Services Administration budget for 1985.

Mr. Chairman and members of the Committee, I will be pleased to answer any questions you may have on the specifics of this budget request.

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## BIOGRAPHY OF ROBERT GRAHAM

NAME : Robert Graham

BIRTHPLACE : Pueblo, Colorado

DATE OF BIRTH: FEBRUARY 15, 1943

EDUCATION : Earlham College, Richmond, Indiana; A.B. Degree, 1965

University of Kansas School of Medicine; M.D. Degree, 1970

Resident in Family Practice, Baptist Memorial Hospital, Kansas City, Missouri, 1974-1975

## PROFESSIONAL ACTIVITIES

1. September 1982 - Present
Administrator, Health Resources and Services Administration, Department of Health and Human Services

2. January 1981 - August 1982
   Acting Administrator, Health Resources Administration, Department of Health and Human Services

3. July 1979 - December 1980
   Professional Staff Member, Subcommittee on Health and Scientific Research, Committee on Labor and Human Services, United States Senate

4. July 1978 - 1979
   Deputy Administrator, Health Resources Administration, Department of Health Education and Welfare, and

   Executive Secretary, Graduate Medical Education National Advisory Committee (GEMANAC)

5. July 1976 - July 1978
   Deputy Director, Bureau of Health Manpower, Health Resources Administration, Department of Health Education and Welfare

6. January 1976 - June 1976
   On staff of Program for Health Management, Baylor College of Medicine, Houston, Texas, and

   Instructor, Department of Community Medicine, Baylor College of Medicine, Houston, Texas

7. February 1973 - January 1976
   Assistant Director, Division of Education, American Academy of Family Physicians, Kansas City, Missouri, and

   Administrative Officer, Society of Teachers of Family Medicine

8. June 1970 - February 1973
   Assistant Administrator for Agency Goals, Health Services and

   Mental Health Administration, Department of Health Education and Welfare, Washington, D.C.

9. 1970-1973; 1976-Present
   Commissioned Officer, Active Duty, United States Public Health Service; Assistant Surgeon General, September 1982 -

## APPOINTMENTS

1. Member, National Board of Medical Examiners (Federal Representative), 1981-1982

2. Consultant, National Academy of Sciences/Institute of Medicine, Social Security Studies, 1974-1976

3. Advisor, Robert Wood Johnson Foundation, Rural Practice Project, 1975-1979

4. Consultant, Bureau of Health Manpower, Office of the Director, 1975-1976

5. Consultant, National Health Service Corps, Office of the Director, 1973-1974

6. Consultant, Study on the Place of Behavioral Sciences in Schools of Medicine, 1969-1970

7. Student Consultant, Carnegie Commission on Higher Education, 1969-1970

## ASSOCIATIONS

1. American Academy of Family Physicians, 1973 -

2. American Medical Association, 1970 -

3. Association of American Medical Colleges, 1968 -

4. Society of Teachers of Family Medicine, 1973 -

5. Society for Health and Human Values, 1969 - (Member, Executive Council, 1971-1975)

## RECENT PUBLICATIONS

1. "Political and Legislative Influences on Primary Care"; Banta, H.D., Graham, R. ; The Mount Sinai Journal of Medicine, Vol. 45, No. 5, Sept.-Oct. 1978

2. "Public Policy Implications of Graduate Follow-Up Studies in Family Practice" ; Graham, R. , The Journal of Family Practice, Vol. 11, No. 5, Oct. 1980

3. "Funding Issues in Primary Care and Family Practice: A Policy Perspective" , Graham, R. , and Lawton, S. , The Journal of Family Practice, Vol. 13, No. 4, Sept. 1981

## PERSONAL INFORMATION

Spouse: Jane E. Henney, M.D.

March, 1984

Health Resources and Services
(Dollars in thousands)

| Health Care Delivery and Assistance | FY 1983 Actual | FY 1984 President's Budget Amend | FY 1984 Appropriation | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|---|---|---|
| MCH block grant (Dollars) | ($477,859)1/ | ($335,000)1/ | $399,000 | ($399,000)1/ | ($407,300)1/ |
| (Positions) | (0)1/ | ((10))1/ | (10) | ((10))1/ | ((10))1/ |
| Primary care block grant | (0)1/ | (407,312)1/ | 5,638 | (5,638)1/ | (533,400)1/ |
| Community health centers | (360,000)1/ |  | 331,362 | (331,362)1/ |  |
| Black lung clinics | (3,120)1/ |  | 3,120 | (3,120)1/ |  |
| Migrant health | (38,093)1/ |  | 42,000 | (42,000)1/ |  |
| Family planning | (124,075)1/ |  | 140,000 | (140,000)1/ |  |
| Subtotal, Primary care | (525,288)1/ | (407,312)1/ | 522,120 | (522,120)1/ | (533,400)1/ |
| Home health | 5,000 | 0 | 5,000 | 5,000 | 0 |
| National health service corps (Dollars) | 88,329 | 96,046 | 91,000 | 91,000 | 67,174 |
| (Positions) | (2,115) | (1,989) | (1,700) | (1,700) | (1,150) |
| Natl hlth service corps scholarships | 15,842 | 0 | 6,300 | 6,300 | 0 |
| Hansen's disease center (Dollars) | 17,868 | 18,183 | 18,183 | 18,449 2/ | 18,694 |
| (Positions) | (297) | (297) | (297) | (297) | (297) |
| Federal employee occupational health (Dollars) | 13,823 | 14,250 | 1,194 | 14,275 3/ | 14,298 |
| (Positions) | (342) | (342) | (26) | (342) | (342) |

| | FY 1983 Actual | FY 1984 President's Budget Amend | FY 1984 Appropriation | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|---|---|---|
| Payment to Hawaii | 1,732 | 1,905 | 2,200 | 2,200 | 1,905 |
| Direct operations, BHCDA (Dollars) | 39,412 | 20,091 | 41,282 | 40,104 4/ | 20,793 |
| (Positions) | (739) | (343) | (779) | (739) | (334) |
| Block grant direct operations (Dollars) | (2,060)1/ | (2,060)1/ | (---) | (2,060)1/ | (1,000)1/ |
| (Positions) | ((40))1/ | ((40))1/ | (---) | ((40))1/ | ((20))1/ |
| Subtotal, BHCDA (Dollars) | 182,006 | 150,475 | 1,086,279 | 177,328 | 122,864 |
| (Positions) | (3,493) | (2,971) | (2,812) | (3,078) | (2,123) |
| Health Professions | | | | | |
| Health professions student assistance | | | | | |
| Loans | 1,000 | 0 | 0 | 0 | 0 |
| Loan repayments and cancellations | 67 | 0 | 0 | 0 | 0 |
| Student Assistance for the Disadvantaged | 0 | 0 | 0 | 0 | 5,000 |
| EFN scholarships | 5,600 | 0 | 5,600 | 5,600 | 0 |
| Subtotal | 6,667 | 0 | 5,600 | 5,600 | 5,000 |
| Health professions institutional asst. | | | | | |
| Financial distress | 7,286 | 5,600 | 5,600 | 5,600 | 4,188 |
| Start-up/conversion | 800 | 0 | 0 | 0 | 0 |
| Subtotal | 8,086 | 5,600 | 5,600 | 5,600 | 4,188 |
| Public health/health administration | | | | | |
| Public health capitation | 4,176 | 0 | 4,838 | 4,838 | 0 |
| PH/Hlth admin. spec projects | 0 | 2,638 | 0 | 0 | 2,000 |
| Health admin. grants | 1,440 | 0 | 1,440 | 1,440 | 0 |
| Public health traineeships | 2,500 | 2,638 | 2,569 | 2,569 | 0 |
| Health admin. traineeships | 480 | 0 | 480 | 480 | 0 |
| Preventive medicine residencies | 1,000 | 1,055 | 1,600 | 1,600 | 1,000 |
| Subtotal | 9,596 | 6,331 | 10,927 | 10,927 | 3,000 |

| | FY 1983 Actual | FY 1984 President's Budget Amend | FY 1984 Appropriation | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|---|---|---|
| Primary care | | | | | |
| Family med/gen. dentistry R & T | 33,996 | 23,738 | 34,000 | 34,000 | 20,000 |
| Gen. internal med. & pediatrics | 11,412 | 12,040 | 17,500 | 17,500 | 9,500 |
| Family med. departments | 7,772 | 7,436 | 7,790 | 7,790 | 5,000 |
| Physician assistants | 4,800 | 4,647 | 4,724 | 4,724 | 0 |
| Subtotal | 57,980 | 47,861 | 64,014 | 64,014 | 34,500 |
| Health prof. special ed initiatives | 2,000 | 7,000 | 3,000 | 3,000 | 3,000 |
| Area health education centers | 17,920 | 14,686 | 17,920 | 17,920 | 10,000 |
| Disadvantaged assistance | 17,240 | 18,188 | 18,188 | 18,188 | 24,000 |
| Health prof. anal. studies & reports | 2,939 | 3,612 | 3,000 | 3,000 | 2,000 |
| Nurse training | | | | | |
| Advanced nurse training | 13,260 | 1,208 | 13,260 | 13,260 | 1,300 |
| Nurse practitioner | 11,760 | 6,041 | 11,760 | 11,760 | 3,000 |
| Special projects | 6,332 | 5,979 | 7,156 | 7,156 | 8,000 |
| Traineeships | 9,600 | 0 | 9,600 | 9,600 | 0 |
| Fellowships | 960 | 0 | 960 | 960 | 0 |
| Research grants | 4,999 | 0 | 9,000 | 9,000 | 2,000 |
| Loans | 107 | 0 | 0 | 0 | 0 |
| Loan repayments and cancellations | 2,505 | 0 | 0 | 0 | 0 |
| Nurse anesthetists | 0 | 0 | 400 | 400 | 0 |
| Subtotal | 49,523 | 13,228 | 52,136 | 52,136 | 14,300 |
| Health education assistance loans | (225,000) | (175,000) | (250,000) | (250,000) | (175,000) |
| Direct operations (Dollars) | 19,121 | 12,527 | 19,470 | 20,446 5/ | 15,305 |
| (Positions) | (316) | (258) | (330) | (330) | (253) |
| Subtotal, BHPr (Dollars) | 191,072 | 129,033 | 199,855 | 200,831 | 115,293 |

| HMO & Resources Development | FY 1983 Actual | FY 1984 President's Budget Amend | FY 1984 Appropriation | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|---|---|---|
| Local planning | 37,731 | 0 | 37,731 | 37,731 | 0 |
| State planning | 19,200 | 0 | 19,200 | 19,200 | 0 |
| Planning methods development | 1,287 | 0 | 1,325 | 1,325 | 0 |
| Health teaching facilities | 32,650 | 3,700 | 800 | 20,814 6/ | 1,200 |
| HMO management training & tech. asst. | 478 | 0 | 0 | 0 | 0 |
| Direct operations (Dollars) | 18,802 | 10,627 | 19,367 | 20,213 7/ | 12,335 |
| (Positions) | (361) | (231) | (361) | (361) | (231) |
| Subtotal, BHMORD (Dollars) | 110,148 | 14,327 | 78,423 | 99,283 | 13,535 |
| Buildings and facilities | 3,113 | 883 | 883 | 5,966 8/ | 0 |
| OA/Program management (Dollars) | 13,667 | 10,782 | 14,711 | 14,986 9/ | 8,025 |
| (Positions) | (217) | (162) | (217) | (217) | (154) |
| Consolidated working fund | -2,756 | 0 | 0 | 0 | 0 |
| Subtotal, HRS (Dollars)10/ | $497,250 | $305,500 | $1,380,151 | $498,394 | $259,717 |
| (Positions)10/ | (4,387) | (3,622) | (3,720) | (3,986) | (2,761) |
| Receipts and reimbursements from Federal funds (Dollars) | -12,913 | -13,056 | 0 | -13,056 | -14,298 |
| (Positions) | (-316) | (-316) | 0 | (-316) | (-342) |
| Recovery of prior year obligations | -6,319 | 0 | 0 | 0 | 0 |
| Unobligated balance start of year | -24,952 | 0 | 0 | -48,714 | -10,048 |
| Unobligated balance transferred | -169 | 0 | 0 | +10,299 | 0 |

| | FY 1983 Actual | FY 1984 President's Budget Amend | FY 1984 Appropriation | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|---|---|---|
| Unobligated balance end of year | +48,714 | 0 | 0 | +10,048 | +10,048 |
| Unobligated balance lapsing | +1,237 | 0 | 0 | 0 | 0 |
| Total Budget Authority (Dollars) | $502,848 | $292,444 | $1,380,151 | $456,971 | $245,419 |
| (Positions) | (4,071) | (3,306) | (3,720) | (3,670) | (2,419) |

1/ These parenthetical entries are proposed for transfer to OASH in 1985.

2/ Includes $266,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs.

3/ Includes $25,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs; amount reflects total obligations.

4/ Includes $882,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs; and a comparable transfer of $2,060,000 and 40 positions to the Assistant Secretary for Health for the Maternal and Child Health and the Primary Care Block Grants.

5/ Includes transfer of $1,401,000 from Program Management to support central services costs previously paid from the former HRA Program Management account; and $976,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs.

6/ Includes $20,014,000 unobligated funds carried over from FY 1983 which will be obligated for construction projects and interest subsidy payments in FY 1984. Excludes $13,569,000 unobligated funds carried over from FY 1983 which are proposed to be transferred for FY 1984 pay costs: $3,270,000 to other HRS activities; $6,904,000 to IHS; $627,000 to the Food and Drug Administration; $1,294,000 to the National Institutes of Health; and $1,474,000 to the Office of the Inspector General.

7/ Includes transfer of $1,598,000 from Program Management to support central services costs previously paid from the former HRA Program Management account; and $846,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs.

8/ Reflects obligations -- includes $5,083,000 unobligated funds carried over from FY 1983.

9/ Excludes transfer of $1,401,000 to BHPr direct operations and $1,598,000 to BHMORD direct operations to support central services costs previously paid from the former HRA Program Management account; includes $275,000 to be transferred from unobligated funds in the Health Teaching Facilities account to cover FY 1984 increased pay costs.

10/ Excludes the following amounts for reimbursable activities carried out by this account: 1983 -- $23,941,000 and 217 positions; 1984 -- $6,959,000 and 63 positions; 1985 -- $21,366,000 and 405 positions.

## INTRODUCTION OF ASSOCIATES

Dr. GRAHAM. Mr. Chairman, thank you very much.

I would like to start my presentation by introducing both those individuals with me here at the table and the three bureau directors who are also in the room.

At my left is Dr. James Walsh, who is the Associate Administrator for Operations and Management of the agency; at my right, Mr. Tony Itteilag, who is the Deputy Assistant Secretary for Budget; and immediately behind me are the directors of the three bureaus whose programs are up for review, Dr. Edward Martin, Bureau of Health Care Delivery and Assistance; Mr. Thomas Hatch, Bureau of Health Professions; and Dr. Daniel Whiteside, Bureau of Health Maintenance Organizations and Resources Development.

From time to time, if it is all right with you, on some of the questions I will ask the Bureau Directors to respond to you directly.

Since the statement is before you for the record, I would simply summarize by saying that the President's request for our activities in fiscal year 1985 reflects program transfers, as you have mentioned, within the Bureau of Health Care Delivery and Assistance. We would maintain the National Health Service Corps and responsibilities in the Hansen's disease program.

In the Bureau of Health Professions we would reorient our emphasis to those highest priority programs related to providing services and access to education for minorities, disadvantaged and the underserved.

Within the Bureau of Health Maintenance Organizations and Resources Development we would continue with our stewardship of the HMO program and our commitment to the Hill-Burton program, free care assurance, and the HUD 242 program.

With that overview, I think it might be most productive to go to the questions that you have this morning.

Senator WEICKER. Senator Andrews, I know you have got a busy schedule. Would you care to lead off?

Senator ANDREWS. I would appreciate it if I could, Mr. Chairman.

Senator WEICKER. Go right ahead.

## CARES PROJECT

Senator ANDREWS. The chairman and I have a good deal of interest in the unique and innovative ways of dealing with the health care needs of this country. As a matter of fact, we are trying to work a schedule out so the two of us can be out at a CARES project operation in western North Dakota in mid-May.

As you know, in 1979 our State received Federal funding for this unique project. The initials stand for the Coordinated Ambulatory Rehabilitation Evaluation Service. It's a good project. Over the 4½ years CARES has sponsored over 32 clinics in the western portion of our State, which is a medically underserved area. Yet it is one of the best in our attempts to get the maximum amount of care at the least amount of cost, because to move these people in 350 miles to a hospital where the care could be given would cost the Federal Government and taxpayers probably five times as much doing this in these outreach areas.

You people supported it well. The program has enabled thousands of North Dakota citizens to receive quality health care for the physically disabled as well as upgrading the ability of the general practitioners out there to deliver this kind of health care.

### FUTURE CARES PROJECTS

Do you perceive future CARES projects in other medically underserved predominantly rural areas?

Dr. GRAHAM. We certainly are very interested in and highly involved in working with individual community health centers and other practitioners in all of the States to make sure that we have the most effective and innovative systems possible to deliver care.

The CARES project, as you pointed out, is a unique one. As a matter of fact, it's funded out of two separate sources of funds, both community health center funds and the MCH set-aside. Whether or not there would be additional combined funding projects, or whether we would be working with community health centers generally to learn from the experience of the CARES project, I wouldn't want to speculate, but I know that the Bureau of Health Care Delivery and Assistance is working now on it. We have memoranda of agreement with over 30 States to work specifically with identifying the highest priority activities in community health primary care and to work with the individual community health centers to make sure that that care is being delivered in a way that most appropriately meets the needs of the community. And I think that the project that you have indicated is one of those projects that we are learning from.

Senator ANDREWS. In a rural State such as ours it's about the best way that we can see of handling patients who live 300 to 400 miles away from a quality rehabilitation center where they don't have accessibility to physical therapists where they live after suffering from a stroke or some other physical handicap. You do think, as I understand it, this is about the best method of meeting that challenge?

Dr. GRAHAM. From all I understand about the CARES project itself, it has been a very successful project and is working very well.

Senator ANDREWS. And you are continuing to keep your interest in it?

Dr. GRAHAM. We are, and as I indicated, trying to learn from the experience in that specific State those elements which may be transferable to other sites and settings.

### RURAL HEALTH CARE

Senator ANDREWS. And you may well transfer parts of this concept to other similarly situated rural States?

Dr. GRAHAM. Yes; that is where I don't want to speculate specifically because I don't know exactly what the interests of the other rural States might be, how those community health centers or rural health systems may be set up, and I wouldn't want to lead you to believe that we are going to have five CARES projects next year. But the principles that we are talking about are principles that we are seeking to carry out in every place.

Senator ANDREWS. I'll put my parochial hat on and say, hey, it's great in our area. It's working well.

Mr. Chairman, might I tell you that what we did in the old days, Chairman Whitten and I on the House side, picked this out of agricultural subcommittee, and it's a unique example of extension service operations where you take what you find out in the land grant institutions, your experiment stations, and through the extension service you extend it out into the field where the needs are. We took that agricultural concept and moved it into medicine and found that it works uniquely well. As you can imagine, we're proud of our baby. Congressman Whitten and I worked together in the House and we started it out and it continued here. We appreciate the fact that you feel it is indeed in fact the success it is.

During the last several months many of my constituents have expressed their concern over the future of rural health care. In the fiscal 1985 budget request many services which are important to rural Americans have either been severely cut or eliminated. These include home health care, which has been eliminated; area health education centers, which are important to medical schools providing health care services to rural areas; and decreases in funding for National Health Service Corps programs.

### FUTURE OF RURAL HEALTH CARE

What do you see for the future of rural health care? Or do we envision a future at all, given these cuts in the 1985 budget?

Dr. GRAHAM. There is no reason to expect that our commitment to working with the issues of rural health care in fiscal year 1985 will be any less than the commitment and the concern that we have today. As you have indicated, there are specific recommendations made in the budget which might change the configuration of the profile of resources available, but the general thrust is that we are trying to approach rural health care with a cooperative endeavor between the Federal Government, the State government, and local communities.

Even with the block grant approach, and obviously one of the major elements that we will be discussing this morning is the creation of a primary care block grant administered by the State, that approach would have a number of these primary care activities rolled up into one activity. There will continue to be a Federal concern and a Federal presence in dealing with the issues of rural health care.

You cited the National Health Service Corps as an area of cut-back, where indeed we will be assigning more individuals through the National Health Service Corps mechanism in 1985 than we have assigned in any previous year. As a result of a reexamination of our assignment priorities over the last 18 months and a look at those areas of the United States which continue to be underserved and have the greatest priority of need for additional practitioners, there will be an increasing proportion of National Health Service Corps assignees who are going into rural areas in 1985.

So although the manner in which the Federal presence is effected in rural areas may change in fiscal 1985 as a result of this budget proposal, I do not believe that the Federal Government is going to be evidencing any less concern about rural health care.

### NURSE TRAINING FUNDS

Senator ANDREWS. Well, let me say that your statement provides a lot more assurance than the actuality of the budget request, and I appreciate that, because these are extremely important programs not just for those of us in rural areas, but also for Indians, native Americans on Indian Reservations, which are chronically underserved. In fact I was in Denver the weekend before last on hearings for Indian health delivery systems and the availability of doctors in those areas. They are hard to come by.

Finally, last year this committee and the Congress funded nurse training at $52 million. This year the administration proposes a level of $14 million. Under this drastic funding reduction what projects will be eliminated in nurse training?

Dr. GRAHAM. We can provide for the record an itemization of the effect, line by line, within the nurse training area on continuation costs or projects whose funding would be reduced or terminated.

[The information follows:]

NURSE TRAINING FISCAL YEAR 1985 CONTINUATION COSTS

[Dollar amounts in thousands]

| Program | 1985 continuations | | 1985 President's budget | | Effect of President budget |
|---|---|---|---|---|---|
| | No. of awards | Dollars | No. of awards | Dollars | |
| Advanced nurse training | 51 | $9,976 | 9 | $1,300 | Fund 9 awards and terminate 42 continuing awards. |
| Nurse practitioner | 38 | 9,487 | 38 | 3,000 | Would partially fund all continuations. |
| Nursing special projects | 58 | 7,507 | 62 | 8,000 | Fund all continuations plus four new awards. |
| Professional nurse traineeships | 98 | 6,400 | | | Would terminate continuations to approximately 2,466 trainees. |
| Nursing fellowships | 116 | 960 | | | Would terminate 116 continuations. |
| Nursing research grants | 80 | 7,973 | 20 | 2,000 | Would fully fund 20 continuations and terminate 60 continuing awards. |

NURSE TRAINING FISCAL YEAR 1985 CONTINUATION COSTS—Continued

[Dollar amounts in thousands]

| Program | 1985 continuations | | 1985 President's budget | | Effect of President budget |
|---|---|---|---|---|---|
| | No. of awards | Dollars | No. of awards | Dollars | |
| Nursing loan cancellations | | [1] $3,700 | | | To be paid when loan cancellations / revolving funds are liquidated. |
| Nurse anesthetists | 24 | 420 | | | Would terminate all continuations to approximately 72 trainees. |
| Total | 4656 | 46,423 | 129 | $14,300 | |

[1] Represents cumulative nursing loan cancellation liability for fiscal year 1983, fiscal year 1984, and fiscal year 1985 due to approximately 1,100 nursing programs.

### NURSING SUPPLY

Senator ANDREWS. Do you have statistics indicating that there is an oversupply of nurses in the country today?

Dr. GRAHAM. The issues of nursing supply that we have dealt with for the last 10 years have been very complex and difficult. We share the view of the study of the Institute of Medicine of approximately 1 year ago that, in general, there is today an adequate general supply of nurses, but there continues to be some inadequate geographical and speciality distribution within the nursing area. Those inadequate supply areas may have more to do with working conditions and financial remuneration than the actual availability of an individual with nurse training to perform the task. What you see reflected in our budget is a prioritization of those programs which we feel still to be of the highest priority for Federal assistance specifically to address the needs of nurse training at the advanced degree level.

### NURSE TRAINING PROGRAMS IN RURAL AREAS

Senator ANDREWS. The pattern of shortages seems to be again in the rural areas and on the Indian reservations. We have, as far as doctors are concerned, an INDMED program where we take the Indians themselves and bring their training up to par and then move them on into medical school, and we are finding we are getting a lot of them back on the reservations. I would suspect that the same type of program would help in the case of nurses.

When you say you are prioritizing what nurse training you are keeping, does that mean that you would, shall we say, supplement those training programs in rural areas or for individuals from rural areas and Indian reservations who have the best chance, because they are familiar with those rural areas and the reservation life, of going back in that area that is demonstrably underserved? Is that the kind of priority you are thinking about when you mention the emphasis on certain facets of the nurse training program?

Dr. GRAHAM. The rural areas would not be specifically addressed by those activities under advanced nurse training and special projects. As we begin responding more to the Indian health aspect, as you have raised it—and obviously you and I have discussed the Indian health budget in a different setting since the Indian Health Service is also part of the agency—what we are trying to do within the Indian Health Service is to identify, site by site, those reasons that make nurse recruitment and nurse retention difficult and try to provide better working conditions to attract more nurses to the Indian Health Service and to retain them in the service of the Indian people once they are there.

As you are well aware, nursing turnover in the Indian Health Service continues to be one of our most substantial problems, but we do feel that we are making some headway there.

Those programs, rather than being addressed by a scholarship program or by a specifically structured program such as INDMED that you referred to for physician training, we are trying to address more at the service unit and area level in terms of identifying nurses who are predominantly native to that part of the country, to increasingly attract them to service within the Indian facilities. I think we are far more likely to find a supply of nurses for the Indian Health Service from those individuals who are native to the part of the country west of the Mississippi.

### NURSING IN UNDERSERVED AREAS

Senator ANDREWS. I totally agree with you, Dr. Graham. I'll carry that one step further. Not only do it with the native Americans who understand and live on and have come from the reservations and are most likely to go back, but the same thing with rural young people. If that is where the shortage of nurses is, as you have just said—and I totally agree with you—then couldn't we keep emphasis on nurse training programs in those institutions that are uniquely training the young people from rural areas who are most likely to go back into the rural underserved areas?

Dr. GRAHAM. With the possible exception of the area health education center program, which would continue in 1985, although at a somewhat reduced level, I would not want to lead you to believing that the nursing programs that we are proposing for 1985 would be specifically addressing the needs of the rural areas.

### NURSING SHORTAGE IN RURAL AREAS

Senator ANDREWS. You said you are having a massive cut in your budget; you said that there is an adequate supply of nurses in most of the country; then you went on to say there is a shortage of nurses on the Indian reservations and in rural parts of the country. And I am saying, OK, fine, you've identified the shortage. Then why not take the lower resources and concentrate on the area where the shortage still exists by training those people who are most likely to go and serve in those areas?

Dr. GRAHAM. What I was trying to explain is that even within the constraints of the budget there are still some programs that we will be pursuing in fiscal year 1985 that address shortage areas. For example, the area health education center program, which involves the training of all types of health professions; and some of the activities of the health career opportunity grant program, which is slated for an increase, where we feel that we will be able to target some activities for individuals who will practice as nurses or other types of health professionals in the rural areas.

I recognize that we may have some disagreement in terms of the budgetary level that we are proposing for 1985 and the interest that you may have, but I think that we can still point to a reasonable maintenance of some rural initiatives within the 1985 budget proposals.

### CENTER FOR NURSING RESEARCH

Senator ANDREWS. That is exactly what I think we have developed in this questioning and what the committee is interested in. If we are going to put less resources in there, certainly those resources ought to be emphasized where the need is greatest, and you seem to agree with that point. So I think we are marching in essentially the same direction.

Last, I have received several letters regarding the possibility of establishing an institute of nursing research at NIH. What is the administration's position on this issue?

Dr. GRAHAM. The position is that the establishment of yet another identified institute at the NIH is not something that we believe to be in the best interest of either the National Institutes of Health or the needs of nursing research, and indeed we would propose that the most effective way to address the needs of nursing research would be within the present context of the Bureau of Health Professions and the Division of Nursing by establishing a center for nursing research within that division.

Senator ANDREWS. Thank you very much, Mr. Chairman.

### CARES PROJECT IN NORTH DAKOTA

Senator WEICKER. I would just like to pin you down on the subject that Senator Andrews first raised because we are going to be looking at it further. What exactly do you envisage in terms of a dollar amount for the CARES project in North Dakota for the fiscal year 1985?

Dr. GRAHAM. I would like to have Dr. Martin respond to that.

Dr. MARTIN. Both the SPRANS and the section 330 grants go through a noncompeting renewal process. So to assure a level of $187,955 is impossible at this time. It is fair to say that the level of services that are being provided by the project will be continued. If you look at the funding history of the project, we have always funded it at the level requisite to continue the activities at not only the same level, but just last year even expanded the activity. Corrected for third-parties that as they collect, and there are increasingly more of them, we are not going to reduce the level of services. I anticipate a grant award will be relatively close to the one we made last year.

Senator ANDREWS. We assumed that that was it, Mr. Chairman, but I appreciate your added emphasis.

Senator WEICKER. Well, these are very nice fellows. I don't mean to cast any aspersions on the ones in this room, but you can't assume anything in this administration or you just might end up with zero.

Senator ANDREWS. Mr. Chairman, I figured that was one of the great things about having you come out to North Dakota in mid-May. Not only will you enjoy the hospitality, but we'll make sure that these people keep the emphasis going. But they have been most cooperative and they have allowed the project to grow in an orderly fashion and continue the type of service that it is giving and, as a matter of fact, expand on that service each year, and we are grateful to you for it.

Senator WEICKER. I am very satisfied with Dr. Martin's response to it. As I said, I am not interested in pinning it down to the last dollar. I think you have answered it the way it can be answered.

Senator ANDREWS. He certainly has, and we want to quit while we are ahead.

### PAYMENT TO HAWAII

Senator WEICKER. Thank you, Senator Andrews.

The subcommittee notes that the 1985 payment to the State of Hawaii for care of leprosy patients, Hansen's disease patients, is proposed to drop from 61 percent of total cost to 50 percent, with a dollar cut of $295,000. I recently made a visit to the Island of Molokai to visit the Kalaupapa Settlement, which receives a portion of the aid. I additionally talked to Department of Health officials relative to the outpatient treatment on the island and was very impressed.

My first question is, why are you proposing to cut back on the payment to Hawaii?

Dr. GRAHAM. I think we feel that essentially a 50–50 sharing arrangement in the maintenance of those activities is a reasonable arrangement.

### PAYMENT FOR CARVILLE FACILITY

Senator WEICKER. What do we do with the payment for the facility at Carville? I have not visited there yet. I intend to do that in the next couple of months. What do we do there?

Dr. GRAHAM. The Carville facility is a Federal facility which serves as both a national and international center not only for services, and indeed the in-patient census of Carville is steady or declining, but increasingly a center for training and research worldwide. Its mission is dramatically different than the mission of the Molokai operation.

### HANSEN'S DISEASE PATIENTS

Senator WEICKER. As I understand it, due to the unrest, and maybe certain other factors involved, in the Pacific basin area there indeed are additional persons coming into the State of Hawaii, and around the Pacific there is an increased incidence of Hansen's disease and for those that are in the State of Hawaii with some form or other of Hansen's disease. I grant you they haven't all ended up at Kalaupapa, but they are certainly receiving treatment in an outpatient sense, and apparently that is on the increase, even though Molokai might not be. You and I can hardly afford to go once every couple of years to Hawaii. It was the first time I've been there, as a matter of fact. How do we expect these people to get to Carville and back? I don't understand that.

Dr. GRAHAM. I don't believe the expectation necessarily is that they will all go to Carville.

Senator WEICKER. What I am saying is I don't understand why mainland United States with a Carville facility, which is a Federal responsibility, and here's the Island of Hawaii, far removed, which is a State also, but yet for some reason or other they are supposed to be on a 50–50 basis. I don't understand that.

Dr. GRAHAM. Let me try to describe the manner in which the Hansen's disease cases are being handled on the mainland. Few if any individuals who are newly diagnosed with Hansen's disease will ever see Carville. We feel very strongly that the appropriate therapy for Hansen's disease now is available within the community, and indeed we should not be incarcerating these individuals.

We work with individual States and local health departments to provide appropriate consultations and backup and some reimbursement on a contract basis for the care of Hansen's disease patients. But on the mainland the care of Hansen's disease patients is a shared responsibility between the Federal Government and the individual State or municipalities, and so I don't think that we are describing for you anything that is markedly different for the State of Hawaii.

Senator WEICKER. Well, I think you would agree, Dr. Graham, the situation of leprosy in Hawaii is a damn sight different than Connecticut.

Dr. GRAHAM. I don't know what the incidence is in Connecticut.

Senator WEICKER. I doubt that we have any.

Dr. GRAHAM. I would suspect that you are not correct, that indeed because of the pattern of immigration we are finding that there are new centers of Hansen's disease incidence throughout the United States. New York State is one example; the Southwestern United States and the Far West. Indeed most of the care for Hansen's disease patients on the mainland now is provided without Federal subsidy; it is not a Federal responsibility.

### INCIDENCE OF HANSEN'S DISEASE

Senator WEICKER. But in just number terms and also, most importantly, in percentage terms, would you agree that probably Hawaii leads all the rest at this time? I'm excluding the Carville facility there.

Dr. GRAHAM. In terms of absolute incidence of Hansen's disease to the total population, the three major areas of Hansen's disease on the mainland, California, Texas, New York—I don't know. Let me check with Dr. Martin.

Senator WEICKER. California would be what, the same immigration from the Pacific basin area, Samoa, et cetera?

Dr. MARTIN. Mr. Chairman, first of all, of the 5,000 or 6,000 Hansen's disease patients in the country, the Carville facility at any one time is taking care of only about 300.

With regard to the sites where care is provided for those people, as Dr. Graham indicated, they are predominantly where the people live.

In terms of the absolute number of patients with Hansen's disease in Hawaii compared to California, Texas, Louisiana, Florida, and New York, it is very clear the bigger States have substantially more cases.

With regard to institutional care, which is the type of care provided at the Molokai site that you visited, there are only two such sites left in the country. In fact, in the Federal site we are trying to reduce the population, as is, I might add, the State of Hawaii on Molokai. So that we are getting out of institutional care and trying to treat people in the community.

It is true that a substantial number of the increased cases over the last 4 or 5 years have been immigrants, not only from Southeast Asia, but from Central and South America, and since the incidence level in the country among Southeast Asians and Central and South America is about the same, the Southwest is very heavily affected. But when you look at where the newly arrived Southeast Asian refugee has settled, you will see that California, Washington, Maryland, and Virginia have had a higher incidence level of Hansen's disease than the State of New York.

I think the distinction Dr. Graham is trying to make is that, while we have regional centers and we provide some assistance through contracts in those areas, the State of Hawaii is the only one where we have a direct subsidy for services, related to the institutional facility at Molokai, in which case as with Carville, we are both trying to move away from institutional care.

In terms of equity the State of Hawaii is comparable to other States with the unique characteristic that it has an institutional population like Carville.

## REDUCTIONS IN PROGRAMS AND POSITIONS

Senator WEICKER. Your in-patient per diem cost certainly is rising, total program cost is rising. I don't think that it is appropriate, at least to the extent of $295,000, to go ahead and make that cut. I am willing to accept your reasoning vis-a-vis the outpatient care and treating Hawaii the same as everybody else. Let's assume that. But I think as long as there is a Molokai and as long as there is a Carville, then you are just going to have to go ahead and contend with that. I know at least at this juncture most of those on Molokai are old and they are there probably because of the stigma they feel attached to their affliction. In any event, as long as that is the case I don't really see that a cut is appropriate.

Your budget request is $271.9 million. That is an 81-percent cut in 1 year, a dollar cut of $1,140,232,000. You propose to make this major change by transferring almost $1 billion in block grants somewhere else by making about $200 million in program cuts and by reducing staff positions by about 1,251.

Is this going to require legislation?

Dr. GRAHAM. I am trying to review all of the proposals that are being made.

I do not believe that any of this would require legislation to accomplish.

I'm sorry. Dr. Martin does point that our proposal for the primary care block would amend the present block. So that would require some legislation for an amendment, although there is a primary care block already on the books. So we would be adding to it.

### BLOCK GRANT PROGRAMS

Senator WEICKER. Would the 15-percent set-aside under the maternal and child health block grant also require legislation?

Dr. GRAHAM. The move of the block grant programs to the Office of Assistant Secretary does not require legislation. The change in the funding pattern, that is, the 15-percent set-aside, would require legislation. So in both the primary care block and the maternal and child health block we would need amendments to those authorizations to accomplish it unless it is done through the appropriations process.

Senator WEICKER. Well, Mr. Itteilag, what say you to all that? We might as well start off where we left off last year. [Laughter.]

Mr. ITTEILAG. Mr. Chairman, the technical aspects of the situation are relatively simple and it's the policy decision that you have to cope with that is more difficult.

Where the block grants are budgeted it does not require legislation because the authorizing statute does not say these block grants must be carried out by the Health Resources and Services Administration. It says they are to be carried out by the Secretary. Therefore, we propose to you a location in the Office of the Assistant Secretary for Health, and we have proposed that before and the Congress either approves that or doesn't approve it.

With respect to the block grants themselves, as has been related, both of them are subject to reauthorization in fiscal year 1985. We are asking for a different complement in the primary care block grant; we are asking for changes in maternal and child health, including doing away with the set-asides; and that is a matter for the legislative committees to contend with.

### REAUTHORIZATION OF BLOCK GRANTS

Senator WEICKER. So how does that affect the budget figures before me if it is not done? What do we do? I'm not an authorizing committee; I'm strictly appropriating for them. I can't accomplish legislation through this committee.

Mr. ITTEILAG. I understand that, Mr. Chairman. This situation, with respect to their reauthorization, is no different than the situation in health professions, health planning. You know the situation there. There are a whole list of programs in the Office of Human Development Services, all of which require new authorization. This situation is no different than one which the committee is traditionally faced with. I take it that if the legislative action is not taken by the time of your markup, then you would not act on these programs and then they would be subject to consideration and continuing resolution.

Senator WEICKER. I don't understand that. We're not going for a continuing resolution or anything. We're going for a bill.

Mr. ITTEILAG. Mr. Chairman, if the programs are not reauthorized by the Congress and if the Appropriations Committee acts as they traditionally have, then you would not consider those unauthorized programs, and then they therefore would be subject to whatever continuing resolution is considered by the Congress.

### BLOCK GRANT TRANSFER

Senator WEICKER. In the same area, you have been aware of our opposition to moving the health block grants from their home agencies to the Office of Assistant Secretary for Health and you have refrained from doing so. You know of our strong opposition to moving family planning to the Assistant Secretary's Office. Yet that is what you have done. How do you explain this inconsistency of response to Congress?

Dr. GRAHAM. I'm sorry, sir. Which specific inconsistency? [Laughter.]

Senator WEICKER. It's great to know that there are that many that we've got to start to pin them down. [Laughter.]

Dr. GRAHAM. You ran through a list of three. I wouldn't want to start on the wrong one.

Senator WEICKER. Family planning.

Dr. GRAHAM. The move of family planning was a decision made by the Secretary. Report language was entered by both the Senate and the House last year, which was taken into consideration by the Secretary, and she has determined that the most effective location for the administration of the family planning program is in the Office of the Assistant Secretary for Health.

Senator WEICKER. I think that what becomes clear to me is that in dealing with this agency the report language just isn't sufficient and we're just going to have to go ahead and move it in line by line, which isn't the way to run a railroad.

Senator Burdick.

### FAMILY MEDICINE RESIDENCY AND TRAINING FUNDING

Senator BURDICK. Thank you, Mr. Chairman.

In the family medicine residency and training program you are proposing a $14 million cut. You would support 135 projects instead of the 260 we are currently funding. What evidence do you have that the 125 projects scheduled to be cut no longer need Federal assistance? Aren't they likely to reapply for continued funding? Why do you think you no longer need it?

Dr. GRAHAM. What is reflected throughout our request in the health professions area is our estimation of the highest priority needs for continued funding in the Federal sector, and indeed we feel that family medicine and the other primary care areas that we have highlighted in those authorities are very much the highest priority. We would not suggest to you that this cut-back is based upon the fact that the programs have access to another source of funds; it's simply reflecting that in a time of necessarily constrained Federal resources this is the level of funds that we can provide for this activity.

Now obviously our long-term effort with a number of the family practice programs is to see them reach a status where because of their success, their strength, their status within the hospital or the university system, that they may not need this special project support from the Federal Government. Indeed, if you look at the total revenues that go into family practice residency training every year, the Federal Government supplies roughly 10 percent of those total revenues, which means that the State sources of funding, that is, reimbursement, hospital funding, university funding are very major considerations in the vitality of the family practice programs.

## FUNDING FOR HEALTH PROFESSIONS EDUCATION

Senator BURDICK. I am impressed with what you said about having a very high priority. Yet you want to cut it $14 million. That isn't logical to me.

Dr. GRAHAM. The logic is that of necessity. The Federal revenues available for health professions education are limited, but within that limit of funds available we have still tried to allocate a level for the continuation of family practice activities in the hopes that we will be able to maintain the initiative of that program.

Senator BURDICK. Your justification states that those schools which do receive continued funds will have to support an increased proportion of their costs from non-Federal sources. It is my understanding that family practice residency programs are not moneymakers at all.

They do not support themselves as well as other specialities for the very reasons we want to encourage family practitioners—they practice less costly preventive medicine in ambulatory settings. Frankly, their services are harder to pad than some other specialities. Do you have evidence that the programs will be able to find non-Federal sources of funding any better next year than they have in the past?

Dr. GRAHAM. I think that varies from program to program. As I indicated in my opening comments, the total portion of Federal support to family practice activities is in the neighborhood of 10 percent, which means that obviously these programs are being successful in securing a wide variety of other sources of funding.

The level of reimbursement for primary care services is something that we are concerned with, and from our vantage point within the Federal structure we try to work with those other individuals responsible for determining fair reimbursement practices to make sure that the delivery of primary care services is adequately and reasonably reimbursed.

There is still a lot of State support and State initiative for family practice programs, which I think is entirely appropriate.

I think other issues that the family practice programs face is their role and their perceived legitimacy within the university and the hospital structure. We seek to assist them in improving that degree of visibility, but I think that is also an issue which the profession itself must address.

### HEALTH CARE FOR "DISADVANTAGED AND MINORITIES"

Senator BURDICK. In your justification it says the administration's goal in this program is to improve the availability of health care for disadvantaged and minorities. In the rural areas we have a terrible physician shortage, and it is the family practice doctors who are moving in to help. In fact, 75 percent of the family practice graduates from the University of North Dakota are now practicing in rural areas. I think improving health care in the rural areas should also be a goal of this program. Do you agree?

Dr. GRAHAM. I think that increasing the appropriate distribution of primary care physicians throughout the United States, not only in rural areas, but in the inner city and the other areas where there are not adequate primary care practicitioners, is something that we have been trying to accomplish for 10 years. I think that the University of North Dakota and a number of other universities are outstanding success stories, and I am pleased that we have had some role in this.

### RURAL HEALTH CARE

Senator BURDICK. In the Health Professions Initiative program the Senate had some report language in the 1984 report urging you to concentrate on geriatric medical training and on improving delivery of health care in rural areas.

I understand you do have ongoing projects in geriatric medicine. What are you doing in the area of rural health other than the effort relating to podiatrists?

Dr. GRAHAM. I can think of specific areas to cite and I would like to have Mr. Hatch, who is the Director of the Bureau of Health Professions, perhaps provide some additional statistics. In addition to podiatry we have the area health education center program, which we have spoken about earlier, and a number of the AHEC facilities are in rural areas. We have both the family practice and the primary care internal medicine pediatrics programs which, to varying degrees, are preparing primary care physicians who are able to practice in areas where the population may not support other types of practitioners.

I think those are the things that we are doing specifically in terms of targeting special project funding to increase the services in rural areas.

We had spoken earlier this morning about the changes that we have made in the assignment policies for the National Health Service Corps where we are trying to identify those areas of the United States which have the highest priority need for health services and which are least likely to be able to find health services resources from any place other than the National Health Service Corps. As a result of changing our assignment policies in the last 18 months an increasing proportion of National Health Service Corps obligors will be going and are going to rural areas.

So those are at least three activities where I feel that we have been moving appropriately to address the legitimate needs of individuals in the rural areas.

Let me ask Mr. Hatch if I have left anything out.

Mr. HATCH. The only other thing I would add to that is that in the nurse practitioner training program we do emphasize the training of nurse practitioners to serve in rural areas, and through the nursing special projects program there are activities that would help in improving training for nurses who serve in rural areas.

Senator BURDICK. In general, the reason I have touched on this subject is because we know that doctors like the city with the bright lights and the higher fees and we have difficulty in the rural areas. I don't think we should be cutting back at all in these programs. That's my view of it.

Thank you. Mr. Chairman.

### INFANT MORTALITY

Senator WEICKER. Thank you, Senator Burdick.

In last year's hearing we asked you about the potential that infant mortality might be rising as a result of recession-related joblessness and loss of health insurance. You told us at the time that the trend line still is down despite the fact that nonwhite infant mortality is almost double that for whites.

I would like to know what you are doing to address the problem of black infant mortality which was at 20 per 1,000 live births in 1981 compared to 10.5 for whites.

Dr. GRAHAM. The trend line for infant mortality overall in the one additional year of data that we have continues to be down. The gap between the infant mortality rate of white and black infants is narrower in that 1 additional year than it was in the prior year.

It is obvious that the issue of infant mortality is a very complex one. The Senate and the House and various committees have continued to look at this. We have been actively involved in numerous conversations with the committees and individual staffs about it. We have ongoing efforts within the Bureau of Health Care Delivery and Assistance with a staff of individuals who I feel are expert, as expert as any in the country, looking specifically at what the research indicates, at what the service programs can accomplish, serving not only as researchers themselves, but providing technical assistance through the MCH project and the other primary care projects that we have, to move into the areas of education, prenatal care, to do everything that we can to continue moving those trend lines down.

As a part of the initiative that the Secretary announced several months ago there will be a task force headed by Dr. Malone from the National Institutes of Health to look at the variances between the health status in the white and minority populations of the United States; there will also be a specific group headed by Dr. Vince Hutchins, who is in the Maternal and Child Health program, to look specifically at the variances in infant mortality.

I think what we have learned in the last year since we had this conversation is that although the trends continue to go in the right direction there also continues to be this variance between black and white infant mortality, and that deserves and will require additional effort and study.

### PRENATAL CARE

Senator WEICKER. You mentioned prenatal care, and yet the Federal funding in this area has dropped drastically. I think the most important aspect of the problem is day care, which is not being received by minority populations, for example, in the inner cities due to the fact that Federal funds aren't there.

Dr. GRAHAM. I can legitimately address that issue within the context of the programs that I represent before you, and I can tell you that both what we are doing in 1984 and part of the logic for the block grant which is proposed in 1985 is to continue to move as aggressively as possible to provide services of all items, including prenatal care, to populations and individuals who are at risk.

We will in 1984, as we did in 1983, have new starts in the community health center program; we will in 1984, as we did in 1983, assign National Health Service Corps obligors to those areas where the populations are at greatest risk and do not have access to any other services.

I think that those program initiatives are entirely consistent with the general strategy that I have laid out to you.

### PRIVATE PRACTICE OPTION IN SHORTAGE AREAS

Senator WEICKER. There is concern that the so-called private practice option is being used by some as a way to serve out an obligation to the National Health Service Corps in a less-than-hardship setting.

What are you doing to discourage this sort of practice and to assure that corps personnel are being assignned to the shortage areas that need them the most?

Dr. GRAHAM. The assignment process being used by the National Health Service Corps this year begins by providing the obligors with the opportunity to identify private practices where they would choose to serve. However, they can choose only from a high priority list, and that list is prepared in consultation with our regional offices and with individual State offices to identify those shortage areas which continue to be verifiable as shortage areas that are in most need of practitioners. I think we can illustrate to you and anyone else who might be interested that the assignment policy this year and the result of that policy will lead to individuals this year and in the subsequent years going only to those areas where there is a true need for their services and that they are not going to some place that might be designatable but does not carry a high priority for the service.

### NATIONAL HEALTH SERVICE CORPS ASSIGNEES

Senator WEICKER. Of the field strength of 3,583 you project for the corps in fiscal 1985 only about 32 percent, or 1,150 persons, will be Federal assignees. This is down from about 51 percent in fiscal 1983. What is your rationale for increasing the private practice side of the corps?

Dr. GRAHAM. What you see increasing are two additional assignment avenues, and I think it reflects the tremendous success that Dr. Martin and his staff have had in prioritizing these locations of service.

The number of Federal assignees will decrease, while the number of assignees in private placement and private practice will increase. The difference between private placement and private practice is that in private placement the individual obligors will serve out their time within the personnel system of a local community health center or other nonprofit entity which is qualified to deliver services and to receive assistance under the NHSC program. That individual is directly responsible to a community board and to the people whom they serve. As a private placement, should they at the end of their service seek to continue in public service, wish to continue as a public health service member, they would receive credit for the time that they have served as a private placement. But other than that, they are entirely within the personnel system of the clinic or the practice where they are working.

A private practice option purely is an individual serving predominantly in a free standing or nonorganized practice site. There are some exceptions to that where they are also part of the personnel system of that site or they are private practitioners but at the end of their obligations they do not have the prerogative of seeking continued Federal employment with credit for that time.

The fact that we are able to place an increasing number of people through the PPA or PPO arrangement into high priority areas reduces the need for Federal dollars to pay their salaries and appropriately puts those salaries on the resource of those individual practices or locations.

### FAMILY PLANNING

Senator WEICKER. Congress provided almost $16 million more for family planning in fiscal 1984 than in the previous fiscal year. Yet we are hearing that some of our regions, including my own region I, initially get less money than in 1983 because you are setting aside $500,000 in each region for national priorities programs. What are these national priorities and how did you arrive at the figure of $500,000 per region or $5 million for the whole country?

Dr. GRAHAM. Mr. Chairman, I do not administer the family planning program and I don't think it would be fair for me to comment.

Senator WEICKER. I understand the money is still under your authority; you're the paymaster.

Dr. GRAHAM. The money is appropriated to the agency. However, the allotments are made to the Office of the Assistant Secretary for Health and the program decisions are made in that office.

Senator WEICKER. Mr. Itteilag, maybe you would like to explain what is going on here.

Mr. ITTEILAG. Mr. Chairman, related to your previous remarks about the report language direction and Dr. Graham's reaction in terms of the Secretary's decision, what is going on in terms of management of the program is that the Secretary has decided that it should be administered by the Assistant Secretary for Health, and that is in fact what is being done.

### HEALTH PROFESSIONS EDUCATION

Senator WEICKER. Once again the administration has proposed a deep slash in health professions education. The cut this time is $91 million, which is almost half the amount made available in fiscal 1984.

What is the rationale of the administration?

Dr. GRAHAM. I think this does bear some on the response that I provided to Senator Burdick earlier. Within a constrained Federal budget we have attempted to allocate funds under the health professions authority to those areas that we feel to be of highest priority, and indeed this budget request on the part of the President is consistent with those requests for these authorities that we have made to you in prior years.

Senator WEICKER. Yes; but that's the problem. I almost jumped in when Senator Burdick was asking you questions. "Within constrained budget"—there is nothing constrained about the defense budget—it keeps on going up and up. When do you people step in and say what is really needed insofar as your area of responsibility is concerned? If I accept your first premise, then the second falls into place very nicely.

Dr. GRAHAM. As you say, when do we step in. You're well aware of the process of budget formulation within the Department, within the executive branch. We do have the opportunity each year as an agency to articulate our view of possible uses of Federal revenues for priority activities. We do that. That's part of our responsibility; that's part of what we're paid for; and we make the most compelling argument that we can in terms of what the priorities are as we see them.

### HEALTH PROFESSIONS REQUEST

Senator WEICKER. Well, since we are on the subject, let's use this as a good example: What was your request for health professions education?

Dr. GRAHAM. I don't have the entire budget table with me. We would be happy to supply for the record, if you would like, the budget documents as they were developed.

You asked for the family medicine request?

Senator WEICKER. Yes.

Dr. GRAHAM. Family medicine request was essentially at the level of the 1984 appropriations, both on the part of the bureau and on my part, of $34 million.

Senator WEICKER. The Institute of Medicine Study on Nursing recommends continued Federal support for nursing programs at a level of $80 million per year. You propose a budget of $14 million, which is a reduction of almost $38 million from the current fiscal year. Again, the same reasoning that applies to the others?

Dr. GRAHAM. Yes, sir.

Senator WEICKER. And what was the original request?

Dr. GRAHAM. Our original request, both Mr. Hatch's request of me and mine of the Public Health Service, was in the neighborhood of around $86 million.

### FUNDING LEVEL

Senator WEICKER. Claudia says "Ask Tony Itteilag at what level it now was cut." I don't have to ask you. I think I know. Was this OMB? In other words, where was this cut to take place? Those are big cuts.

Mr. ITTEILAG. Mr. Chairman, in fact in this case it was not the Office of Management and Budget; it was the Assistant Secretary for Health and the Secretary who reached this decision. Within the context of the overall dollars with which we had to work, we felt that this was as much as we could put in this area.

Senator WEICKER. Dr. Brandt, you can get ready to go ahead and respond to this when you step before the committee, which will be a matter of minutes.

I'll tell you one thing, though, it's good to know, Dr. Brandt, that you and the Secretary don't pay any more attention to your own people than you do the Congress. [Laughter.]

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

All right, Dr. Graham. I have further questions for response to the record, both from myself and from other members of the committee, and I thank you very much for your time.

Dr. GRAHAM. Thank you very much, Mr. Chairman.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### HEALTH PROFESSIONS EDUCATION

Question: The Subcommittee wishes to know what recommendations were made within HHS by administrators or other agency heads and by HHS to OMB for each program under Health Professions Education. In addition to showing each amount recommended, please provide the rationale for each such amount, explaining, for example, why it was proposed, what objectives were sought, and how many additional persons would be retrained and/or served.

Answer: The following table reflects the separate FY 1985 budget requests for Health Professions Education programs by the Bureau of Health Professions, the Health Resources and Services Administration and the Department, Health and Human Services.

These FY 1985 budget requests were developed to coincide with new legislative proposals for health professions and nurse training program. As the legislative proposals became more solidified, the budget request was revised to meet the objectives of such new legislation. Legislative proposals at this time are being reviewed by the Department and the Office of Management and Budget and we expect them to be ready soon for submission to Congress.

In the past, State and local governments, health professions schools, professional organizations, and the Federal government have taken major responsibility for addressing health professions education and practice problems. This Administration believes that the non-Federal groups should continue to play a central role in this field, and that the Federal Government should support and stimulate specific high priority health professions activities as needed to accomplish national health goals.

Long term trends in the health field supported by Federal efforts have led to steadily increasing supplies of health professionals. Accompanying this increase has been an increase in the number of health professions educational programs. At the same time, cumulative Federal contributions to health professions and nursing student loan funds, combined with rapidly growing amounts of HEAL loan guarantees, have put in place a foundation of Federal health professions student aid which will amount to more than $381 million in 1985. Because of this, programs providing general support to health education to increase the numbers of practitioners are no longer the area of greatest need.

It is in recognition of these trends and in light of overall funding constraints that the budget proposes focusing of health education funds on the most pressing problems of quality, specialty and geographic distribution of health professionals, and opportunities for the disadvantaged and minority populations.

Overall, approximately two-thirds of the health professions budget addresses barriers which make access to health education and health care difficult or impossible for underrepresented groups. In addition, the Health Professions request supports National priority special projects. These include programs to continue support for training primary care personnel, improving the skills of health practitioners in methods of health promotion and disease prevention, and support for nursing research projects which relate to nursing practice, education, and delivery of services. Also, the budget reflects a refocusing on the needs of minorities and the disadvantaged and national priority projects for nursing programs.

This is the overall FY 1985 rationale for funding Health Professions programs. The various levels of funding requested by the Bureau, Agency, PHS and the Department were the recommendations made at these organizational levels with consideration given to the needs and the resources available to these organizational components.

BUREAU OF HEALTH PROFESSIONS
1985 Budget History Table
($ in thousands)

| Health Professions | BHPr Request | HRSA Request | PHS Request | DHHS Request |
|---|---|---|---|---|
| H.P. Student Assistance | | | | |
| Loans | -- | -- | -- | -- |
| Loan Cancellations | $ 221 | $ 221 | -- | -- |
| Loan Repayment | 100 | 100 | -- | -- |
| Exceptional Financial Need Scholarships | 5,600 | 5,600 | -- | -- |
| Student Assistance for the Disadvantaged | -- | -- | -- | -- |
| Loan Revolving Funds | (49,000) | (49,000) | (49,000) | (49,000) |
| PHS Loan Repayment | $ 9,000 | $ 4,200 | -- | -- |
| HEAL | | | | |
| (guaranty limit) | (275,000) | (275,000) | (275,000) | (275,000) |
| (borrowing authority) | (--) | (--) | (--) | (--) |
| appropriations | -- | -- | -- | -- |
| Subtotal, HP Student Assistance | $14,921 | $10,121 | -- | -- |
| H.P. Institutional Assistance | | | | |
| Financial Distress | $ 4,188 | $ 4,188 | $ 4,200 | $ 4,188 |
| Conversion | -- | -- | -- | -- |
| Subtotal, HP Institutional Assist | $ 4,188 | $ 4,188 | $ 4,200 | $ 4,188 |
| Health Promotion/Disease Prevention | | | | |
| Public Health Capitation | -- | -- | -- | -- |
| PH/Health Administration Special Project | $ 5,680 | $ 5,680 | $ 2,800 | $ 2,800 |
| Public Health Traineeships | 4,713 | 4,713 | -- | -- |
| Health Administration Grants | -- | -- | -- | -- |
| Preventive/PH Dentistry Program | 500 | 500 | -- | -- |
| Preventive Medicine Residencies | 1,107 | 1,107 | $ 1,100 | 1,107 |
| Subtotal, Hlth Prom/Dis Prevention | $12,000 | $12,000 | $ 3,900 | $ 3,907 |
| Primary Care | | | | |
| Family Med/Gen Dentistry Residency&Trng | $34,000 | $34,000 | $20,000 [1] | $20,000 [1] |
| General Internal Medical & Pediatrics | 16,500 | 16,500 | 9,500 [2] | 9,500 [2] |
| Family Medicine Departments | 7,800 | 7,800 | 5,000 | 5,000 |
| Physician Assistants | 4,875 | 4,875 | -- | -- |
| Subtotal, Primary Care | $63,175 | $63,175 | $34,500 | $34,500 |
| H.P. Special Educational Initiatives | | | | |
| Health Promotion/Disease Prevention | $ 5,250 | $ 5,250 | -- | -- |
| Prevention & Promotion-AH Personnel | (1,900) | (1,900) | | |
| Veterinary Medicine-Special Projects | (700) | (700) | | |
| Dental Health | (1,650) | (1,650) | | |
| Nutrition | (1,000) | (1,000) | | |
| Geriatric/Long Term Care | 4,000 | 4,000 | -- | -- |
| Economies in HP Teaching & Practice | 4,657 | 4,657 | -- | -- |
| Remote Site Clinical Training | (1,350) | (1,350) | | |
| Research on Utiliz. of Hlth Care Pers. | (900) | (900) | | |
| Research on Utiliz. of PH Personnel | (800) | (800) | | |
| Podiatric Special Training | (1,107) | (1,107) | | |
| Financial/Reimbursement Projects | (500) | (500) | | |
| Continuing Education/Special Projects | 4,600 | 4,600 | -- | -- |
| Associated/Dental Health | (2,600) | (2,600) | | |
| Medicine | (2,000) | (2,000) | | |
| Faculty Development | 900 | 900 | -- | -- |
| Minorities & Disadvantaged Initiatives | -- | -- | -- | -- |
| Subtotal, HP Special Education Init | $19,407 | $19,407 | -- | -- |

## BUREAU OF HEALTH PROFESSIONS
### 1985 Budget History Table
($ in thousands)

| | BHPr Request | HRSA Request | PHS Request | DHHS Request |
|---|---|---|---|---|
| Area Health Education Centers | $ 18,800 | $ 18,800 | $11,800 | $ 11,854 |
| Disadvantaged Assistance | $ 32,000 | $ 32,000 | $12,000 3/ | $ 18,188 |
| HP Analytical Studies & Reports | $ 5,440 | $ 5,440 | $ 2,000 | $ 2,000 |
| General Mandate | | | | |
| Coordinating Systems (Linkage) | $ 1,700 | $ 1,700 | -- | -- |
| Collaborative/Technical Asst. Activ. | 1,100 | 1,100 | -- | -- |
| Subtotal, General Mandate | $ 2,800 | $ 2,800 | -- | -- |
| Subtotal, Health Professions | $172,731 | $167,931 | $68,400 | $ 74,637 |
| Nurse Training | | | | |
| Advanced Nurse Training | $ 12,000 | $ 12,000 | $ 1,300 | $ 1,300 |
| Nurse Practitioner | 13,000 | 13,000 | 4,000 | 4,000 |
| Nursing Special Projects | 17,000 | 17,000 | 7,000 | 5,000 |
| Professional Nurse Traineeships | 13,000 | 13,000 | -- | -- |
| Nursing Fellowships | 3,000 | 3,000 | -- | -- |
| Nursing Research Grants | 10,000 | 10,000 | -- | 2,000 |
| Research Grants, Contracts, Co-op Agrmnt | (7,000) | (7,000) | (--) | (2,000) |
| National Nursing Research Center | (3,000) | (3,000) | (--) | (--) |
| Collaborative Education Grants&Contracts | 5,000 | 5,000 | -- | -- |
| Cooperative State Initiatives | 5,000 | 5,000 | -- | -- |
| Supply/Distribution Requirements | 2,000 | 2,000 | -- | -- |
| Nursing Student Loans | -- | -- | -- | -- |
| Loan Revolving Funds | (17,900) | (17,900) | (17,900) | (17,900) |
| Nursing Loan Cancellations | 6,321 | 6,321 | -- | -- |
| Nursing Loan Repayment | 100 | 100 | -- | -- |
| Subtotal, Nursing | $ 86,421 | $ 86,421 | $12,300 | $ 12,300 |
| Subtotal | $259,152 | $254,352 | $80,700 | $ 86,937 |
| Direct Operations, BHPr | $ 22,008 | $ 23,757 | $14,800 | $ 14,560 |
| GRAND TOTAL | $281,160 | $278,109 | $95,500 | $101,497 |
| TOTAL (FTP) Positions | 385 | 433 | 258 | 253 |
| TOTAL FTEs | | (330) | (300) | (288) |

1/ $17.6 million for residencies and $2.4 million for faculty development. Begin phase out of residency stipends in FY 1985.

2/ $6.4 million for residencies and $3.1 million for faculty development. Begin phase out of residency stipends in FY 1985.

3/ Based on funding approximately 120 projects at $100,000 each.

## BUREAU OF HEALTH PROFESSIONS
### 1985 Budget History Output Table

| Health Professions | BHPr Request | HRSA Request | PHS Request | DHHS Request |
|---|---|---|---|---|
| H.P. Student Assistance | | | | |
| Loans, No. of Students Assisted | -- | -- | -- | -- |
| Loan Cancellations, No. of Schools | 120 | 120 | -- | -- |
| Loan Repayment, No. of Students | 20 | 20 | -- | -- |
| Exceptional Financial Need Scholarships, No. of Students | 350 | 350 | -- | -- |
| Student Assistance for the Disadvantaged, No. of Schools | -- | -- | -- | -- |
| Loan Revolving Funds, No. of Students | 24,500 | 24,500 | 24,500 | 24,500 |
| PHS Loan Repayment, No. of Agreements | 346 | 163 | -- | -- |
| HEAL, No. of Borrowers | 20,626 | 20,626 | 20,626 | 20,626 |
| H.P. Institutional Assistance | | | | |
| Financial Distress, No. of Schools | 4 | 4 | 4 | 4 |
| Conversion, No. of Schools | -- | -- | -- | -- |

| | BHPr Request | HRSA Request | PHS Request | DHHS Request |
|---|---|---|---|---|
| Health Promotion/Disease Prevention | | | | |
| Public Health Capitation, No. of Schools | -- | -- | -- | -- |
| PH/Health Administration Special Projects, No. of Projects. | 110 | 110 | 50 | 50 |
| Public Health Traineeships, No. of Projects | 48 | 48 | -- | -- |
| Health Administration Grants, No. of Projects | --. | -- | -- | -- |
| Preventive/PH Dentistry Program, No. of Projects | 5 | 5 | -- | - |
| Preventive Medicine Residencies, No. of Projects | 74 | 74 | 74 | 74 |
| | | | | |
| Primary Care | | | | |
| Family Med/Gen Dentistry Residency&Trng, No. of Projects... | 239 | 239 | 179 | 179 |
| General Internal Medical & Pediatrics, No. of Projects | 65 | 65 | 57 | 57 |
| Family Medicine Departments, No. of Projects | 49 | 49 | 49 | 49 |
| Physician Assistants, No. of Projects | 34 | 34 | -- | -- |
| | | | | |
| H.P. Special Educational Initiatives - No. of Projects | | | | |
| Health Promotion/Disease Prevention | 37 | 37 | -- | -- |
| Prevention & Promotion-AH Personnel | (14) | (14) | (--) | (--) |
| Veterinary Medicine-Special Projects | (7) | (7) | (--) | (--) |
| Dental Health | (8) | (8) | (--) | (--) |
| Nutrition | (8) | (8) | (--) | (--) |
| Geriatric/Long Term Care | 16 | 16 | -- | -- |
| Economies in HP Teaching & Practice | 26 | 26 | -- | -- |
| Remote Site Clinical Training | (13) | (13) | (--) | (--) |
| Research on Utiliz. of Hlth Care Pers | (4) | (4) | (--) | (--) |
| Research on Utiliz. of PH Personnel | (4) | (4) | (--) | (--) |
| Podiatric Special Training | (4) | (4) | (--) | (--) |
| Financial/Reimbursement Projects | (1) | (1) | (--) | (--) |
| Continuing Education/Special Projects | 32 | 32 | -- | -- |
| Associated/Dental Health | (28) | (28) | (--) | (--) |
| Medicine | (4) | (4) | (--) | (--) |
| Faculty Development | 12 | 12 | -- | -- |
| Minorities & Disadvantaged Initiatives | -- | -- | -- | -- |

BUREAU OF HEALTH PROFESSIONS

1985 Budget History Output Table

| | BHPr Request | HRSA Request | PHS Request | DHHS Request |
|---|---|---|---|---|
| Area Health Education Centers, No. of Projects | 12 | 12 | 5 | 5 |
| Disadvantaged Assistance, No. of Projects | 206 | 206 | 120 | 137 |
| HP Analytical Studies&Reports, No. of Activities/Actions... | 4,916 | 4,916 | 3,983 | 3,983 |
| | | | | |
| General Mandate | | | | |
| Coordinating Systems (Linkage), No. of Projects | 9 | 9 | -- | -- |
| Collaborative/Technical Asst. Activ, No. of Projects | 7 | 7 | -- | -- |
| | | | | |
| Nurse Training | | | | |
| Advanced Nurse Training, No. of Projects | 77 | 77 | 8 | 8 |
| Nurse Practitioner, No. of Projects | 88 | 88 | 38 | 38 |
| Nursing Special Projects, No. of Projects | 113 | 113 | 40 | 40 |
| Professional Nurse Traineeships, No. of Trainees | 5,317 | 5,317 | -- | -- |
| Nursing Fellowships, No. of Fellowships | 333 | 333 | -- | -- |
| Nursing Research Grants | | | | |
| Research Grants, Contracts, Co-op Agrmnt, No. of Projects. | 70 | 70 | -- | -- |
| National Nursing Research Center, No. of Projects | -- | -- | -- | -- |
| Collaborative Education Grants&Contracts, No. of Projects.. | 50 | 50 | -- | -- |
| Cooperative State Initiatives, No. of Projects | 33 | 33 | -- | -- |
| Supply/Distribution Requirements, No. of Projects | 20 | 20 | -- | -- |
| Nursing Student Loans, No. of Students Assisted | -- | -- | -- | -- |
| Loan Revolving Funds, No. of Students Assisted | 22,375 | 22,375 | 22,375 | 22,375 |
| Nursing Loan Cancellations, No. of Schools | 990 | 990 | -- | -- |
| Nursing Loan Repayment, No. of Students | 125 | 125 | -- | -- |

## THE BUDGET REQUEST

Question: I'm very disturbed at what you plan to do with the budget for the Health Resources and Services Administration. Your budget request is $271.9 million. That is an 81% cut in one year -- a dollar cut of $1,140,232,000. You propose to make this major change by transferring almost $1 billion in Block Grants somewhere else, by making about $200 million in program cuts and by reducing staff positions by about 1,251. Why take a perfectly fine federal agency, a major component of the U.S. Public Health Service, and tear it apart this way?

Answer: The proposed changes to the Health Resources and Services Administration are not expected to "tear it apart." The Administration's rationale for the various changes are as follows:

1. Transfer of the administration of the Primary Care and Maternal and Child Health Block Grants to OASH ($941.7 million included in 1985 OASH request)

   The further consolidation of primary care categorical programs, coupled with the administrative management of the block grants by a single Public Health Service Agency, and relaxation of requirements imposed on the States, is expected to enhance efforts to allow States more opportunity and flexibility in improving the effectiveness of health services.

2. Major program reductions and reduced staff:

   -- National Health Service Corps (-$23.8 million and -550 positions) - Reduction reflects increased emphasis on obligors fulfilling their obligation in private placement assignments or in private practice option sites and a related decrease in the number of Federally-salaried Corps members. The total field strength does not decrease, but rather, increases from 1984 total field strength of 2,960 to 1985 field strength of 3,583.

   -- Health Professions Training (-$85.5 million and -77 positions) - Long-term trends in the health field have led to steadily increasing supplies of health professionals. Because of this, programs providing general support to increase the numbers of practitioners are no longer the area of greatest need. It is in recognition of these trends and in light of overall funding constraints that the budget proposes focusing of health education funds on the most pressing problems of quality and distribution. To do this, the 1985 budget is focused on overarching, high priority issues such as:

      o increasing opportunities for the economically disadvantaged and minorities

      o increasing the numbers of health care providers serving minorities and the underserved

-- Health Planning (-$65.1 million and 130 positions) - Reflects the proposed elimination of federal support to health planning programs in 1985. This program has been continued under Continuing Resolutions for two years (without authorizing legislation). The re-proposed elimination of health planning is consistent with the Administration's efforts to reduce the role of the Federal government in regulating the health industry.

Question: What evidence can you give that this massive change will not simply create confusion and hardship among those dependent on the humanitarian programs involved?

Answer: The transfer of the administration of the Maternal and Child Health (MCH) and Primary Care Block Grants to the Office of the Assistant Secretary for Health (OASH) will not affect the services provided to those dependent upon these funds. Though the Primary Care Block Grant (PCBG) is proposed to be revised and expanded in 1985, implementation of similar consolidations for the other blocks has been highly successful in continuing needed services. Also, the 1985 budget does request a 2.2% increase over 1984 total dollars for those programs to be included in the PCBG. Similar funding increases are proposed for the other PHS Block Grants in 1985. These increases, coupled with our experience with the MCH Block, lead us to believe that the implementation of the PCBG will not create confusion and hardship among those dependent upon these programs.

Question: What is this proposed budget doing to staff morale at your agency?

Answer: I think that staff morale remains generally high in HRSA. This may be due to the fact that we have already implemented several previous budget reductions without massive separations of employees.

## COMMUNITY HEALTH CENTERS I

Question: We often hear it said that Community Health Centers (CHC) compare favorably to other providers in terms of efficiency and effectiveness.

To what extent do the centers diminish the need for more costly hospital services -- and is there any related cost savings to Medicaid from this?

Answer: Centers are awarded CHC grant dollars to support the provision of community-oriented medical care, including primary care and priority supplemental services. The comprehensive range of services which grant dollars enable the centers to provide include health promotion and disease prevention strategies based on specific community needs.

In the past few years, four case studies of CHC users and non-users in four different States have demonstrated the favorable impact of the comprehensiveness of services and continuity of source of care provided by CHC on both hospital utilization and on the total annual per capita cost of care. Three general statements can be made:

(1) CHC users demonstrated lower per capaita hospital admission rates, fewer hospital days per year, and a shorter average length of stay than non-users.

(2) CHC users demonstrated slightly higher numbers of ambulatory care visits per year than non-users, but the total cost to the Medicaid system was less for CHC users. Non-users of CHCs tended to use more expensive sources of care.

(3) Total annual Medicaid reimbursements for all services were significantly lower for CHC users than for non-users. CHCs did prove to save the Medicaid system money.

## INFANT MORTALITY

Question: In last year's hearing, we asked you about the potential that infant mortality might be rising as a result of recession-related joblessness and loss of health insurance. You told us at the time that the trend line still is down despite the fact that non-white infant mortality is almost double that for whites.

Where do we stand on this matter a year later?

What are you doing to address the problem of black infant mortality which was at 20 per 1,000 live births in 1981 compared to 10.5 for whites.

Dr. Brandt, the Assistant Secretary for Health, testified that the Department had set itself a goal to reduce overall infant mortality to 9 per 1,000 live births by 1990 but that he believed "We will achieve that goal significantly before 1990." Do you still believe that will happen?

Answer: Even though there has been a steady decrease in the U.S. infant mortality rate, in any given year there are individual States which may experience increases and, subsequently, decreases in the following year. It is expected, of course, that States and communities regularly will monitor data from their jurisdictions and take appropriate actions, including revision in their priorities and resource allocations in response to changing needs.

Assuming the same average percent decline for Infant Mortality Rate (IMR) of the past decade, the projected estimate of IMR for the Nation as a whole will fall well within the target of 9 infant deaths/1,000 live births. Extrapolation of he Black rate, however, yields an IMR of 13.5 as opposed to the target of 12 deaths/1,000 live births. Currently, our attention is especially directed to the disparity in infant mortality rates between our Black and White populations. The following table illustrates the history of this disparity.

**Infant Mortality rates by race and ratio of rates for black infants to rates for white infants: United States, 1960 -**

**[Rates per 1,000 live births in specified group. Beginning 1970 excludes data for nonresidents of the United States]**

| | Rate | | | | Ratio Black/White |
|---|---|---|---|---|---|
| | | | All other | | |
| Year | All races | White | Total | Black | |
| 1982[1]...... | 11.2 | --- | --- | --- | --- |
| 1981[2]...... | 11.9 | 10.5 | 17.8 | 20.0 | 1.90 |
| 1980......... | 12.6 | 11.0 | 19.1 | 21.4 | 1.94 |
| 1979......... | 13.1 | 11.4 | 19.8 | 21.8 | 1.91 |
| 1978......... | 13.8 | 12.0 | 21.1 | 23.1 | 1.92 |
| 1977......... | 14.1 | 12.3 | 21.7 | 23.6 | 1.91 |
| 1976......... | 15.2 | 13.3 | 23.5 | 25.5 | 1.91 |
| 1975......... | 16.1 | 14.2 | 24.2 | 26.2 | 1.84 |
| 1974......... | 16.7 | 14.8 | 24.9 | 26.8 | 1.81 |
| 1973[3]...... | 17.7 | 15.8 | 26.2 | 28.1 | 1.77 |
| 1972......... | 18.5 | 16.4 | 27.7 | 29.6 | 1.80 |
| 1971......... | 19.1 | 17.1 | 28.5 | 30.3 | 1.77 |
| 1970......... | 20.0 | 17.8 | 30.9 | 32.6 | 1.83 |
| 1969......... | 20.9 | 18.4 | 32.9 | 34.8 | 1.89 |
| 1968......... | 21.8 | 19.2 | 34.5 | 36.2 | 1.88 |
| 1967......... | 22.4 | 19.7 | 35.9 | 37.5 | 1.90 |
| 1966......... | 23.7 | 20.6 | 38.8 | 40.2 | 1.95 |
| 1965......... | 24.7 | 21.5 | 40.3 | 41.7 | 1.93 |
| 1964......... | 24.8 | 21.6 | 41.1 | 42.3 | 1.95 |
| 1963[4]...... | 25.2 | 22.2 | 41.5 | 42.8 | 1.92 |
| 1962[4]...... | 25.3 | 22.3 | 41.4 | 42.6 | 1.91 |
| 1961......... | 25.3 | 22.4 | 40.7 | 41.8 | 1.86 |
| 1960......... | 26.0 | 22.9 | 43.2 | 44.3 | 1.93 |

[1] Provisional.

[2] Figures are subject to change. These are preliminary figures based on a special interim tabulation of data from the 1981 mortality file.

[3] Based on a 50-percent sample of deaths.

[4] Figures by race exclude data for residents of New Jersey because this State did not require reporting of the item for these years.

Our approaches to this issue are many and varied because, with infant mortality, we are dealing with a multi-faceted issue. Included in our approaches are: health education efforts having to do with developing information on proper care, proper diet, avoidance of harmful practices and substances; resource allocation support efforts through CHCs and National Health Service Corps assignments and the Maternal and Child Health Block Grant; and expanding our knowledge through research and special project activities by the National Institute for Child Health and Human Development and the Division of Maternal and Child Health.

Our belief is that responsibility for improving infant health through service delivery activities, basically, lies with the local communities and the States. At the Federal level, responsibility includes identifying and communicating significant trends, doing research and supporting appropriate projects and activities; and, making certain limited resource allocations.

Dr. Brandt recently testified before the House Committee on Energy and Commerce on this subject and dealt, at length, with the scope and nature of this problem and the opportunities to help resolve it. A copy of this testimony has been provided to the Committee.

(Clerk's Note: The statement follows.)

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## STATEMENT OF EDWARD N. BRANDT, JR., M.D.

I am here today with Dr. Carolyne K. Davis, Administrator of the Health Care Financing Administration, to discuss an issue of great concern to our Nation--infant mortality.

As a Nation, we can be proud of our achievements in improving maternal and infant health. For example, the provisional infant mortality rate for 1983 was 10.9, the lowest rate in history. Babies born at the present time will live healthier and longer lives than ever before; yet just over one percent will not survive their first year. However, there remain disturbing geographical variations and disparities between sub-populations in our Nation. We are concerned about these disparities as are the States, localities, professional groups, and others.

A brief look at some recent statistics will provide an important background for our discussion today. There are 52 million women of reproductive age in this country. They had a total of 3.6 million live births in 1983. Included in those numbers are at-risk groups:

- o nearly 200,000 babies born to school-age adolescents under 18 years of age, including nearly 10,000 to girls under the age of 15;
- o nearly a quarter of a million infants who weigh less than 2500 grams at birth;
- o over 900,000 infants born to women who smoked during pregnancy; and
- o over one million infants born to women who drank during pregnancy.

Almost 40,000 live-born infants died in 1983 before reaching their first birthday.

## National Trends in Infant Mortality

Infant mortality is defined as the death of a live-born infant under one year of age and is usually expressed as a rate (IMR) per 1000 live births. Infant mortality rates in this country have been declining at a rapid pace since the late 1960s as shown on this chart. As I mentioned, the provisional rate of 10.9 infant deaths per 1000 live births in 1983 is the lowest rate thus far recorded for our Nation. The IMR among black infants remains almost twice that of white infants. In 1981, the latest year for which race-specific data are available, the national IMR was 11.9 per 1,000 live births, while the IMR was 10.5 for white infants and 20.0 for black infants. These rates represent IMR declines from 1980 of 4.5 percent for white and 6.8 percent for black infants. The continuing high black IMR is indeed a major concern. This problem, however, is not of recent origin. It has been with us for many decades.

All this is said to make clear that interpreting infant mortality data must be done thoughtfully, carefully, and objectively. Reducing infant mortality is a complex task with no simple and quick solution. We are continuing to examine the factors associated with infant mortality to identify opportunities for appropriate interventions.

## National trends in the incidence of low birth weight (LBW)

Low birth weight (less than 2500 grams) is the most important risk factor associated with infant mortality. Compared to the decline in infant mortality, the incidence of LBW has declined relatively slowly during the 1970s as shown by the chart. Since the progress toward reducing LBW has been less than desired, we are continuing to seek new understanding regarding this problem. As a result of our efforts, we have come to understand that the prevention of LBW is complex. No single factor accounts for all of the variation in birth weight and hence, no single intervention will be effective. In fact, the combination of many variables such as demographic characteristics of the mother, medical and obstetric-history, physical stature of mother, smoking and alcohol use, nutrition, as well as gestational age, explain only a portion of the birth weight variation. Better understanding of the biomedical and social factors related to LBW are essential to the development of effective intervention strategies.

Here again, blacks continue to be twice as likely as whites to deliver a low birth weight infant. There have been many studies of the black/white differential in pregnancy outcome over the past several decades. Among the reasons cited for poor outcome among blacks are the following:

- o higher proportions of teenage, high parity, and out-of-wedlock births;
- o lower socioeconomic status;
- o higher incidence of anemia and hypertension; and
- o lack of adequate nutrition.

Findings from various analyses illustrate the complexity of the relationships among factors associated with a greater risk of LBW. For example, maternal smoking and alcohol consumption are associated with reduced birth weight. Yet data on married women from the 1980 National Health Interview Survey and the 1980 National Natality Survey show that black women are somewhat less likely than white women to smoke or drink.

Even when several factors are controlled simultaneously, black women continue to be twice as likely as white women to have low birth weight infants. Based on an analysis of 1981 birth certificate data, the rate of low birth weight infants among college educated, married women, age 25-29 having their second child who began prenatal care in the first trimester was estimated to be 2.3 for whites and 5.6 for blacks.

The fact that mature, married, college educated black women who received prenatal care are still twice as likely as their white counterparts to deliver a low birth weight infant indicates that the black/white disparity represents much more than a simple phenomenon. Therefore, single focused approaches may not realize the significant reduction in the black/white gap we all hope to achieve.

## Important Principles

Let me note some principles that may be self-evident, but nonetheless are important if we are to succeed in further reducing infant mortality and preventing low birth weight:

- assuring that the mother's health is optimal at the time of pregnancy through the provision of proper medical care, with special attention to appropriate treatment and control of diseases such as diabetes, hypertension, and anemia;
- avoiding behavior known to be related to untoward pregnancy outcomes, such as smoking, alcohol consumption, and drug abuse, and improper nutrition;
- assuring that the pregnancy has been planned to coincide with optimal maternal age and interval between pregnancies.

Reducing infant mortality is a national problem that requires the efforts of all members of our society for solution. The individual woman should assume responsibility to seek proper medical care and comply with medical advice, the local community should provide support systems, the health care professionals should provide appropriate scientifically based advice and care, the State authorities should define areas of need and plan to meet those needs supported by such programs as the health block grants and State and local funds.

## Prenatal Care

In this light, some comments on the relative effectiveness of various interventions to improve pregnancy outcome and infant health become important. I believe quality prenatal care is an important intervention opportunity. There is little question as to the value of prenatal care in improving the health of the pregnant woman and preventing or reducing the complications of pregnancy and labor such as eclampsia. It has been asserted that more prenatal care for high risk women will also reduce LBW. However, the task of determining the effectiveness of prenatal care for improving fetal health and reducing low birth weight has been difficult. In fact, the Institute of Medicine has formed a committee, with whom we are working closely, to investigate the whole area of prevention of low birth weight.

The ten years between 1970 and 1980 showed steady progress toward narrowing the black/white gap in receipt of early prenatal care and a significant trend toward achieving high rates of women receiving early care. Nonetheless, only 62 percent of black women delivering in 1981 received prenatal care in the first trimester compared to 79 percent of white women. These 1981 natality data showed a very small decline in receipt of early care among black women, representing a departure from the upward trend of the previous decade. It is difficult to draw firm conclusions about the reasons for the slight decline since it appears that it occurred uniformly among both high and low risk black women. For the U.S. as a whole, no subgroup of black women showed a decline of more than one percentage point. We are now analyzing State trends in prenatal care.

When dealing with these recent trends in prenatal care, it is important to recall an issue I touched on earlier. Recent studies suggest that the quality and content of prenatal care may be the most important ingredient. Yet, despite our increased understanding of risk factors, such as smoking, we still know comparatively little about how to modify at-risk behavior. We need to expand our knowledge in order to target our resources and develop effective responses to prevent low birth weight.

## Objectives for the Nation

As you are aware, in 1980 "Objectives for the Nation" were established to call attention to specific areas where work must be done to improve health, prevent disease and reduce the burden of disability.

Assuring all infants a healthy start in life and enhancing the health of their mothers are important components of our measurable objectives for the improvement of the health of Americans. The quantitative objectives selected for the Pregnancy and Infant Health area focus on lowering infant, neonatal and perinatal mortality rates, reducing low birth weight, and improving health for pregnant women and infants.

A number of objectives in several of the other priority areas, such as immunization, family planning, smoking control, nutrition, control of sexually transmitted diseases, and alcohol and drug misuse prevention have significant implications for improving the health of mothers and newborn children. However, the single priority area most immediately and uniformly relevant to our areas of mutual concern and interest today is that which deals with pregnancy and infant health. (See chart)

Assuming the same average percent decline for IMR of the past decade, the projected estimate of IMR for the Nation as a whole will fall well within the target of 9 infant deaths/1,000 live births. Extrapolation of the black rate yields an IMR of 13.5 as opposed to the target of 12 deaths/1,000 live births.

Between 1970 and 1980, LBW declined modestly by 14 percent with the reduction in the proportion of full-term LBW infants accounting for 75 percent of this decline. At the current rate of progress, we, at this point, expect to fall short of our targets. As a result of concern about the low birth weight problem, I have recently established a Task Force on LBW within the context of the 1990 Objectives. An important component of this initiative is accelerated research activity. In fact, the National Institute of Child Health and Human Development has developed an expanded research agenda for the prevention of LBW. Our infant mortality efforts will coordinate with Secretary Heckler's Task Force on minority health concerns, which will deal with the broad issues affecting the health of minorities in this country.

At this point, it is important to emphasize the joint responsibilities shared by the individual, the health professionals, the State and local health authorities, and the Federal Government. Specifically, the role of the Federal Government includes the following:

- education of the public
- information dissemination to health professionals
- research leading to improved interventions
- assistance to State and local authorities via technical assistance and funding via block grants and categorical programs, and
- direct provision of services such as the Indian Health Service

We need to emphasize the importance of combining the family planning program with other primary care activities in the Primary Care block grant which we continue to urge the Congress to adopt. There are a number of advantages to an integrated approach.

- promotion of good health practices by women who are becoming sexually active, including immunization against rubella, counseling regarding health effects of lifestyle choices, proper spacing of pregnancies and appropriate care for those women with chronic diseases such as diabetes, hypertension, sexually transmitted diseases, and genetic illnesses such as sickle cell disease
- the fact that women for whom contraceptive methods fail are already in the system for care and prenatal care can be implemented promptly and early
- early implementation of counseling as to pregnancy
- follow-up on the child to ensure good well-baby care, immunizations, etc. can be implemented

The PHS has many activities and programs that strive to reduce infant mortality, all of which have been important in the progress we have made in the last 15 years. The following examples highlight some of these activities:

Service Programs

- The Maternal and Child Health (MCH) block grant helps each State assure access to maternal health services of good quality and to reduce infant mortality--especially by providing prenatal care and preventive services as well as delivery and postpartum care. Through this consolidation of program and funding activities, States have full control and authority over substantial resources which they can allocate in the light of their own needs assessments and priorities. Results from the GAO draft report on implementation of the MCH block grant in 13 States, indicate an increased emphasis on services relating to improved pregnancy outcome, including prenatal and postpartum care.

- The MCH program has supported a wide range of activities to strengthen the capacity of the States to improve health status outcomes for mothers and children. For example, special project funds were awarded to States with excessive infant mortality (and adolescent pregnancy) to assist in the development of regionalized perinatal systems. These projects, known as the Improved Pregnancy Outcome (IPO) projects, are currently funded in 20 States and their activities are now being integrated with MCH block grant programs. Continuation of these services by the States, and the decline in infant mortality indicate that these IPO projects, along with other factors, have had positive results.
- The National Health Service Corps and the MCH program are working jointly to identify obstetric and pediatric underserved areas in the U.S. utilizing rates of low birth weight and postneonatal mortality to place about 100 obstetricians and 200 pediatricians to provide direct services in underserved at-risk areas.
- Community Health Centers and Migrant Health projects provide prenatal care to medically underserved pregnant women and have been associated with significant improvement in black infant mortality rates.
- The Indian Health Service, working with tribal health departments, private practitioners and national professional organizations, provides comprehensive maternal and child health services. Emphasis is on early identification of pregnant women and entrance to care, especially for the teenage population, to permit delivery of proper services and early health education. We have made great progress in reducing Indian infant mortality rates and are, therefore, conducting an analysis of IHS-MCH data to understand better what factors have contributed to our progress and to identify the areas in which we must do more work.
- Through the Adolescent Family Life Program we fund projects to prevent adolescent pregnancy by reaching adolescents before they become sexually active, to discourage adolescent sexual activity,

and to minimize the adverse consequences for pregnant adolescents and their children. The program funds demonstration projects that offer care and prevention services in different delivery settings. After final evaluations of each model program have been completed, local communities will be able to adopt proven models.

Research Activities

- o The National Institute of Child Health and Human Development (NICHD) has assigned the highest priority to research on the low birth weight infant, its etiology, prevention, and treatment. NICHD has developed an expanded research initiative to prevent low birth weight. The initiative includes research on intrauterine growth retardation (fetal growth factors, biological predictors of fetal growth and Perinatal Emphasis Research Centers); research on premature labor (biochemistry of labor and premature rupture of membranes); and research on environmental factors (nutritional, socioeconomic, risk-taking behavior, physical activity, and working conditions). The initiative includes a cooperative network of maternal-fetal medicine units for clinical studies, educational efforts, joint efforts with other agencies and foundations, and a National Low Birth Weight Advisory Committee.
- o The Federal response to the knowledge we have gained over the last decade on the effects of alcohol consumption during pregnancy has consisted of (1) vigorous public education, (2) heightened professional education, and (3) continued support of research. At the present time, the National Institute on Alcohol Abuse and Alcoholism supports 21 fetal alcohol research projects to address such issues as the effects of binge or episodic drinking, the effects of alcohol exposure during critical periods of fetal development, mechanisms causing the adverse effects of alcohol on infants, and long-range development of children born to mothers who drank during pregnancy.

This only represents a sample and not the full range of PHS research activities related to infant mortality.

Data and Surveillance

- The Centers for Disease Control will initiate this summer a National Infant Mortality Surveillance which will provide birth weight-specific mortality rates for various specific maternal characteristics.
- The National Center for Health Statistics (NCHS) is undertaking a study to assess the feasibility of establishing a national system of linked birth and death records which will provide an improved data base for monitoring infant mortality trends.
- NCHS is linking the 1980 and 1981 National Death Index with the 1980 National Natality Survey (NNS) in order to prepare special analyses on infant mortality. For example, infant mortality rates will be generated for multiple data items in the NNS, such as birth weight, maternal complications of pregnancy, and maternal smoking.
- Further, NCHS is developing an International Collaborative Effort to identify what we can learn from our international neighbors, especially those countries with the lowest infant mortality rates. The first step will be a meeting later this year with eminent researchers from those countries to select the specific topics for research and to develop appropriate protocols.

Public and Professional Education

- The PHS was one of the six founders of the Healthy Mothers, Healthy Babies Coalition, a group representing voluntary, health professional and State, local and Federal governmental agencies concerned about the health of mothers and babies. While the Coalition acknowledges the primary importance of the delivery of health services, its purpose is to improve the quality and availability of public education on prenatal and infant care. Its goals are to:
  - promote public awareness and education in preventive health habits for all pregnant women;

— develop networks for sharing information among groups concerned about improving the health of mothers and babies;

— distribute public education materials on topics related to improving maternal and child health; and

— assist the development of local Healthy Mothers, Healthy Babies Coalitions.

o Under the auspices of the Healthy Mothers, Healthy Babies Coalition, the PHS has produced and distributed, in English and Spanish, radio spots, posters, pamphlets, newspaper columns, teacher guides, and bibliographies to clinics serving low income areas, WIC offices, health departments, and schools nationwide. A program to promote breast feeding is under way, jointly sponsored by five medical professional organizations, and a special committee of the Coalition is addressing the educational needs of low income women.

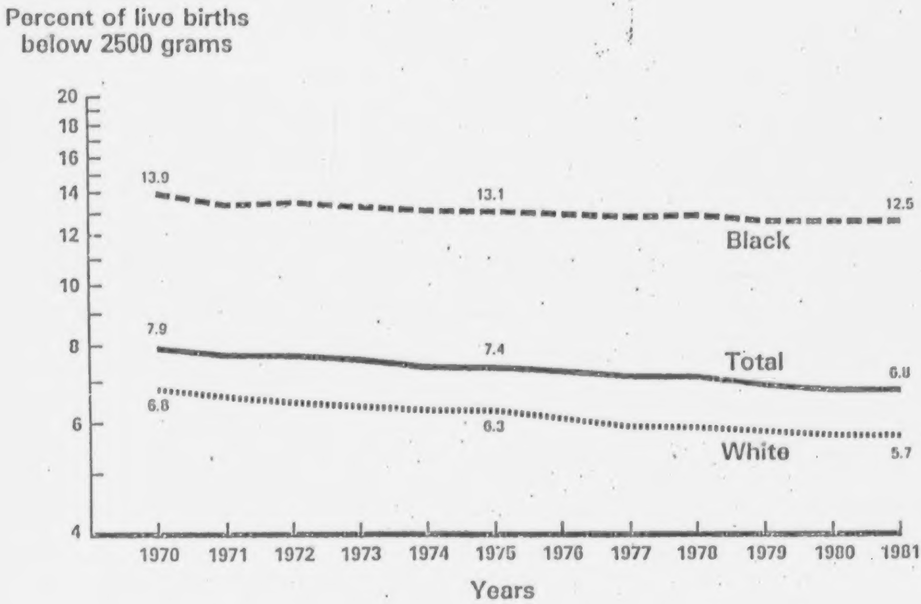
o The Food and Drug Administration (FDA) is preparing a final rule establishing labeling requirements for infant formulas which will provide information to health care professionals and consumers, including those who cannot read English, on the appropriate preparation and use of infant formulas to assure the health and well-being of infants. The agency is also preparing a proposal to revise the infant formula nutrient requirements, based on the 1983 recommendations of the Committee on Nutrition of the American Academy of Pediatrics. Further, FDA is preparing a final rule to establish quality control, nutrient, and labeling requirements for infant formulas that are intended for infants with special medical and dietary needs.

Today, I have discussed various issues surrounding infant mortality and low birth weight and have provided you with a brief listing of some of our current activities relating to these important topics. The Federal efforts I have identified are just one part of the full range of Federal, State, local and private sector programs necessary to meet the

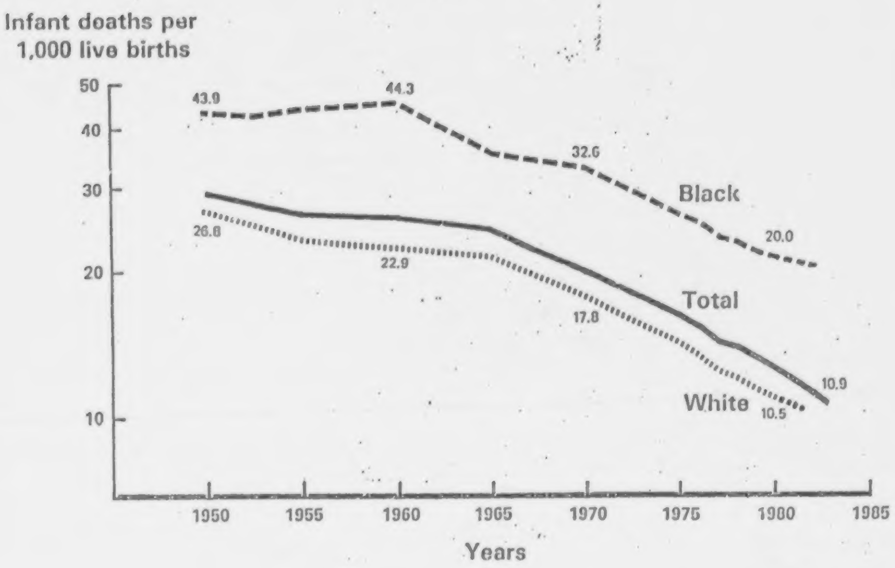
1990 Objectives. By no means are these the only efforts. We know well that many community and State agencies are undertaking innovative efforts to improve their infant mortality rates. We have received very recently a report on such efforts which I will submit for the record. Promoting and protecting the health of the newborn is the best investment we can make in the future good health of the American people.

Thank you. I will be happy to answer any questions you may have.

**LOW BIRTH WEIGHT RATIOS**
1970-81



## INFANT MORTALITY RATES
1950-83



## Lead HHS Agencies for Objectives

| Category | HHS Agency/Office |
|---|---|
| **Preventive Services** | |
| High Blood Pressure Control | National Institutes of Health |
| Family Planning | Office of Population Affairs |
| Pregnancy and Infant Health | Health Resources and Services Administration |
| Immunizations | Centers for Disease Control |
| Sexually Transmitted Diseases | Centers for Disease Control |
| **Health Protection** | |
| Toxic Agent Control | Senior Advisor for Environmental Health |
| Occupational Safety and Health | Centers for Disease Control |
| Accident Prevention and Injury Control | Centers for Disease Control |
| Fluoridation and Dental Health | Centers for Disease Control |
| Surveillance and Control of Infectious Diseases | Centers for Disease Control |
| **Health Promotion** | |
| Smoking and Health | Office on Smoking and Health |
| Misuse of Alcohol and Drugs | Alcohol, Drug Abuse, and Mental Health Administration |
| Nutrition | Food and Drug Administration |
| Physical Fitness and Exercise | President's Council on Physical Fitness and Sports |
| Control of Stress and Violent Behavior | Alcohol, Drug Abuse, and Mental Health Administration |

## MIGRANT HEALTH

Question: Hundreds of thousands of migrant and seasonal farmworkers are dependent on the migrant health program for their health care. You propose to terminate this program as we know it by including it in a large block grant.

What assurance would we have that there will continue to be migrant health centers available to serve this needy population should your block grant proposal be approved? (Note: The number of persons served is expected to rise from 394,000 in 1983 to 460,000 in fiscal 1984.)

Answer: Under the proposed expanded Primary Care Block Grant, States would receive sufficient funds to enable them to continue current programs within their jurisdictions at an increased dollar level and to tailor these programs to the particular needs of their residents.

Question: To what extent do states currently contribute to the support of the migrant health centers program?

Answer: The Migrant Health Program has no specific requirement for State-matching of funds. However, most Migrant Health Centers/Projects attempt to maximize the coordination of local health services for migrant and seasonal farmworkers and their families, and may develop agreements with State and local agencies for sharing the delivery of services. There are various States, such as Pennsylvania, Puerto Rico, North Carolina, Tennessee, Oklahoma, Kansas, Nebraska and Colorado, in addition to other private nonprofit entities within those States, which receive Migrant Health funds to deliver services to migrant and seasonal farmworkers.

Question: How and where do migrant and seasonal farmworkers obtain health services in areas where there are no migrant health centers?

Answer: Migrant and seasonal farmworkers generally do not seek out health delivery services due to language, cultural and life-style barriers. In areas where CHCs exist, they can obtain health services from these centers. Where there are no CHCs nor Migrant Health Centers, they generally do obtain health services from hospitals only when emergency situations occur.

## NATIONAL HEALTH SERVICE CORPS

Question: The Subcommittee is a little unclear about some of your plans for the National Health Service Corps field program in fiscal 1985.

For fiscal 1985, you are planning a 21 percent increase in your total field strength compared to only a 3 percent increase between fiscal 1983 and fiscal 1984. What accounts for this sharp increase?

Answer: FY 1985 is the peak year for output from the NHSC Scholarship Program. We expect about 1,468 scholarship recipients to be available for placement in the NHSC in FY 1985, or 308 more than estimated for FY 1984. resulting in a similar increase in the NHSC total field strength.

## NATIONAL HEALTH SERVICE CORPS PRIVATE PRACTICE

Question: As you know, there is concern that the so-called Private Practice Option is being used by some as a way to serve out an obligation to the National Health Service Corps in a less-than-hardship setting.

To what extent are you reducing or eliminating Federal presence in the worst health manpower shortage areas as a result of building up private rather than Federal practice?

Answer: With regard to the impact of this policy on the NHSC presence in the worst Health Manpower Shortage Area (HMSAs) (01-02), we believe it will have little, if any, effect. All Federal assignees are placed in high need HMSAs which have demonstrated an inability to recruit primary care providers. These areas are predominantly 01-02 HMSAs.

Question: There is the Private Practice Option--and thee is the Private Placement. What's the difference? What's the exact authority for Private Placement?

Answer: Private Placement Assignment (PPA) scholarship recipients are assigned to CHC and Migrant Health Centers as private practitioners. Funding for these individuals is provided to the centers through Federal grants to offset salary and benefit costs. Private practice assignees are members of the NHSC, are subject to the personnel system of the entity to which they are assigned, and receive at least the same income as they would have received as Federal civil service employees of the NHSC.

The legislative authority for the PPA may be found in Sections 331(a)(1)(C), 331(d)(3) and 333(d)(1) of the Public Health Service Act as amended.

The purpose of converting Federally employed NHSC providers to private practice in Community and Migrant Health Centers is to better coordinate the use of NHSC manpower and Primary Care grant funds within the intent of their legislative authorities, and to reserve Federal assignees for high need urban and rural locations which, despite vigorous recruiting efforts, are unable to attract primary care providers. The conversion process has the effect of relieving the Centers of the burden of multiple personnel systems, and it places all providers under their direct administrative and clinical control. It also permits the Centers to stabilize their operating costs and plan for revenues to offset these costs.

Private Practice Option (PPO) scholarship recipients enter into a written agreement with the Secretary under which the individual agrees to engage for a period equal to the remaining service obligation in the full-time private clinical practice (including service as a salaried employee in an entity directly providing health services) of his profession. PPO participants may not discriminate against individuals on the basis of their ability to pay for health services or because payment for health services will be made under Medicare or Medicaid.

The legislative authority for the PPO may be found in Section 338C of the Public Health Service Act as amended.

## PAYMENT TO HAWAII

Question: The Subcommittee notes that the 1985 Payment to the State of Hawaii for care of leprosy patients is proposed to drop from 61 percent of total cost to 50 percent, with a dollar cut of $295,000. I recently made a visit to the Island of Molokai to view the Kalaupapa Settlement, which receives a portion of this aid, and was very impressed. Is the State ready and able to pick up these additional costs?

Answer: The appropriation for Payment to the State of Hawaii is for partial support for care and treatment of persons afflicted with Hansen's Disease (HD). The Federal portion has averaged from 50 to 55 percent of the cost of the Hawaii's HD program.

This grant provides a portion of the costs for inpatient care at Kaluapapa Hansen's Disease facility on Molakai. The Kaluapapa settlement stopped admitting new patients in 1969. Since that time, all new patients in Hawaii are treated on an outpatient basis and receive inpatient care at Hale Leahi when necessary.

In addition to this grant, the Division of National Hansen's Disease Programs is providing an additional $384,468 in FY 1984 and FY 1985 under the Regional HD Center program. In late FY 1983, a contract was signed between the Division and the State of Hawaii to enable the State to greatly expand its Hansen's disease activities. The contract provides funding for outreach services, drug serveillance, special footcare and footwear, a patient information system, and public health training and education. These additional services will enable the State to greatly improve its outpatient program and to expand its emphasis on providing outpatient rather than inpatient care.

In the past, the State of Hawaii has always borne its share of the costs of the program and there is every expectation that it will in the future.

## CUTS IN PUBLIC HEALTH

Question: Page 132 of your justification shows that you are reducing by 72 percent your health promotion/disease prevention programs under public health.

I have been told that at least one school of public health the capitation program helps maintain an adequate faculty, and traineeships are the backbone of the school's assistance to low income students. This is probably true at most of these schools. Why, therefore, do you propose to terminate the capitation and public health traineeship programs?

Answer: It is the Administration's position that basic institutional support should come from State and local funds, tuition, and private sources. For financially needy health professions students, there are loan programs, such as the HEAL program, in which the student pays no principal or interest while he or she is in training. In addition, the Administration has proposed a new program, Student Assistance for the Disadvantaged, which gives additional capital contributions to the Health Professions Student Loan revolving funds in schools with relatively high proportions of minority students. Also, the Administration has proposed another new program, Public Health/Health Administration Special Projects, which includes traineeship authority for these students.

Question: You keep submitting budget requests for a Public Health Special Projects program, requiring legislation. Have you ever sent up the legislation and, if so, what is its status?

Answer: In 1983, the Administration proposed to revise the public health/health administration special project authority to take the place of existing Public Health Capitation grants. That bill was introduced on March 24, 1984, in the Senate as S.963; at present, no action has been taken on this bill by the Senate or the House. The Administration's proposed new legislation for health professions programs contains essentially the same program for public health/health administration special projects as contained in Senate Bill S.963. This reauthorization proposal for all health professions programs will be submitted to Congress shortly.

## HEALTH PROFESSIONS CUT

Question: Once again the Administration has proposed a deep slash in Health Professions Education. The cut this time if $91 million, which is almost half the amount made available in fiscal 1984. The big push in the Federal government and elsewhere is disease prevention, yet you propose to cut Preventive Medicine residencies by some 37 percent from the FY 1984 level. Why is this and what you the continuation costs of the program in fiscal 1985?

| | |
|---|---|
| FY 1984 Appropriation | $1,600,000 |
| FY 1985 Request | 1,000,000 |

Answer: State and local governments and other entities are expected to provide increased support for these programs. The continuation costs for this program in FY 1985 are $2.3 million.

Question: Please provide a table showing the fiscal 1985 continuation costs for all of the health professions programs under your jurisdiction.

Answer: The following is a table showing the costs to continue "on-going" Health Professions programs in FY 1985:

| Program | FY 1985 Continuation Costs |
|---|---|
| H.P. Financial Distress | $ 4,188,000 |
| H.P. Stud. Asst. for the Disadvantaged | --- |
| H.P. Loan Cancellations | 100,000* |
| Public Hlth/Hlth Admin. Special Proj | --- |
| Public Hlth/Hlth Admin. Traineeships | 1,598,000 |
| Family Medicine Residency & Training | 29,071,000 |
| General Dentistry Residency | 1,993,000 |
| General Internal Med. & Pediatrics | 15,414,000 |
| Family Medicine Departments | 6,721,000 |
| Physician Assistants | 4,260,000 |
| Preventive Medicine Residencies | 2,328,000 |
| H.P. Special Educ. Initiatives | 2,934,000 |
| Area Health Education Centers | 15,003,000 |
| Disadvantaged Assistance | 19,080,000 |
| H.P. Analytical Studies & Reports | 2,839,000 |
| Advanced Nurse Training | 9,976,000 |
| Nurse Practitioner | 9,487,000 |
| Nurse Special Projects | 7,507,000 |
| Nurse Traineeships | 6,400,000 |
| Nurse Anesthetists | 420,000 |
| Nurse Fellowships | 960,000 |
| Nurse Research Grants | 7,973,000 |
| Nursing Loan Cancellations | 3,700,000 |
| TOTAL | $151,952,000 |

*Amounts required to meet cumulative (FYs 1984 and 1985) obligations.

Question: Also please include in the table data from available sources showing the shortages of trained personnel in each area.

Answer: No comprehensive set of statistics on shortages of trained personnel exists at the present time. This is due, at least in part, to a variety of definitions of what constitutes a shortage. The attached table gives the most recent figures for health manpower shortage areas (HMSAs). These areas are defined in terms of adjusted population to practitioner ratios, for example, 3,500 people per primary care physician. However, the Bureau of Health Professions is in the process of performing a comprehensive review of the HMSAs, and approximately 20 percent of the primary care HMSAs will no longer be designated. Thus the figures in Table 1 slightly overstate the current shortages as measured by the HMSA criteria.

Another indicator is the vacancy rates reported by employers. Table 2 shows how hospital vacancy rates have changed over the past 3 years. Hospital employment has grown more slowly than in previous years and vacancy rates are somewhat lower. Registered nurses, occupational and physical therapists have vacancy rates which continue to be higher than other professions.

The vacancy rate data are also consistent with data on unemployment rates. Table 3 shows little unemployment among occupations with high vacancy rates such as RNs, but much higher unemployment among other occupations such as aides and orderlies.

Table 1. Health manpower shortage areas: number, population and additional practitioners needed, for geographic areas, population groups and facilities (as of June 30, 1983)

| | Number of designations | Population in designated areas | Estimated unserved population 1/ | Practitioners needed to remove designations |
|---|---|---|---|---|
| Primary medical care totals... | 2,150 | 44,929,439 | 18,336,000 | 5,884 2/ |
| Geographic areas............ | 1,949 | 42,600,244 | 16,801,508 | 5,260 |
| Population groups........... | 117 | 1,920,242 | 1,161,025 | 335 |
| Facilities.................. | 84 | 408,953 | 373,467 | 289 |
| Dental totals................. | 980 | 21,915,621 | 9,083,114 | 2,076 3/ |
| Geographic areas............ | 895 | 20,599,828 | 8,248,396 | 1,836 |
| Population groups........... | 64 | 1,083,241 | 702,841 | 153 |
| Facilities.................. | 21 | 232,552 | 131,877 | 87 |
| Vision care................... | 273 | 13,779,100 | -- | 406 4/ |
| Podiatry...................... | 1,403 | 87,303,414 | -- | 1,745 5/ |
| Pharmacy...................... | 132 | 1,135,440 | -- | 174 6/ |
| Veterinary care............... | 623 | 14,584,875 | -- | 1,598 7/ |
| Psychiatry.................... | 376 | 36,242,900 | -- | 1,760 8/ |

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1/ The estimated unserved population is computed by multiplying the number of practitioners in the area by the population to practitioner ratio required for designation, and subtracting this figure from the area population.

2/ The number of additional primary care physicians required to achieve a population-to-primary care physician ratio of 3500:1 (3000:1 where high needs are indicated) in all designated primary care shortage areas, resulting in their removal from designation.

3/ The number of additional dentists required to achieve a population-to-dentist ratio of 5000:1 (4000:1 where high needs are indicated) in all designated dental shortage areas, resulting in their removal from designation.

4/ The number of additional vision care practitioners needed to eliminate the difference between visits required and visits supplied, if each provides 3000 visits.

5/ The number of additional foot care practitioners needed to achieve a population-to-practitioner ratio of 28,000:1.

6/ The difference between the number of pharmacists required under the shortage criteria and the current supply of pharmacists in the area.

7/ The number of additional food animal veterinarians needed to achieve a veterinary livestock units-to-veterinarian ratio of 10,000:1.

8/ The number of additional psychiatrists needed to achieve a population-to-psychiatrist ratio of 20,000:1.

Table 2. Total Full-Time Equivalent Employment, and
Vacancy Rates for U.S. Registered Hospitals

| | Full-Time Equivalent Employment | | | Percent Change | | Vacancy Rates | | |
|---|---|---|---|---|---|---|---|---|
| | 1980 | 1981 | 1982 | 1980-81 | 1981-82 | 1980 | 1981 | 1982 |
| Total Hospital Personnel | 3,491,659 | 3,661,438 | 3,772,853 | 4.9 | 3.0 | 4.9 | 4.4 | 3.3 |
| Administrators & Asst. Administrators | 25,442 | 34,586 | 36,225 | 35.9 | 4.7 | 2.5 | 2.5 | 2.0 |
| Physicians | 53,925 | 53,348 | 50,465 | 0.1 | -5.4 | 3.8 | 8.4 | 3.2 |
| Physicians Assistants 1/ | N/A | 3,316 | 3,464 | N/A | 4.5 | N/A | 7.5 | 3.7 |
| Dentists | 4,001 | 3,969 | 3,510 | -0.8 | -11.6 | 1.7 | 2.6 | 3.1 |
| Registered Nurses | 693,382 | 697,555 | 740,240 | 0.6 | 6.1 | 8.9 | 7.6 | 5.3 |
| Nurse Practitioners | N/A | N/A | 4,081 | N/A | N/A | N/A | N/A | 3.9 |
| Licensed Practical Nurses | 258,409 | 263,159 | 267,510 | 1.8 | 1.7 | 6.7 | 5.8 | 3.7 |
| Ancillary Personnel | 345,885 | 382,439 | 388,736 | 10.6 | 1.6 | 3.7 | 3.0 | 2.6 |
| Other Nursing Service Personnel | 205,220 | 179,868 | 162,296 | -12.3 | -9.8 | 3.5 | 3.4 | 2.5 |
| Medical Record Administrators | 7,112 | 7,254 | 7,302 | 2.0 | 0.7 | 2.2 | 2.6 | 2.2 |
| Medical Record Technicians | 35,363 | 36,397 | 36,970 | 2.9 | 1.6 | 2.6 | 2.7 | 2.0 |
| Pharmacists - Licensed | 27,796 | 29,689 | 31,442 | 6.8 | 5.9 | 2.7 | 3.1 | 2.8 |
| Pharmacy Technicans | 22,787 | 24,997 | 26,722 | 9.7 | 6.9 | 3.3 | 3.3 | 2.7 |
| Medical Technologists | 83,281 | 85,324 | 90,714 | 2.4 | 6.3 | 3.5 | 3.4 | 2.3 |
| Other Laboratory Personnel | 73,286 | 74,748 | 75,004 | 2.0 | 0.3 | 2.9 | 2.8 | 2.6 |
| Dietitians | 14,083 | 14,403 | 14,283 | 2.3 | -0.8 | 3.0 | 2.7 | 2.5 |
| Dietetic Technicians | 36,829 | 32,134 | 30,336 | -12.7 | -5.6 | 2.1 | 2.6 | 1.8 |
| Radiographer (Radiologic Tech.) | 50,424 | 53,662 | 55,596 | 6.4 | 3.6 | 2.9 | 2.9 | 2.1 |
| Radiation Therapy Technologists | 4,423 | 4,007 | 4,414 | -9.4 | 10.2 | 5.2 | 3.9 | 3.7 |
| Nuclear Medicine Technologists | 6,781 | 7,226 | 7,334 | 6.6 | 1.5 | 4.3 | 3.8 | 3.1 |
| Other Radiologic Personnel | 33,707 | 32,025 | 32,511 | -5.0 | 1.5 | 2.4 | 2.3 | 1.9 |
| Occupational Therapists | 7,400 | 7,968 | 8,633 | 7.7 | 8.3 | 8.5 | 6.9 | 5.7 |
| Occupational Therapy Assistants and Aides | 4,251 | 4,214 | 4,007 | -0.9 | -4.9 | 6.0 | 4.2 | 4.2 |
| Physical Therapists | 15,790 | 16,876 | 17,392 | 6.9 | 3.1 | 9.1 | 7.3 | 6.9 |
| Physical Therapy Assisants & Aides | 14,534 | 14,876 | 15,187 | 2.4 | 2.1 | 3.3 | 2.8 | 2.2 |
| Speech Pathologists/audiologists 1/ | N/A | 3,855 | 4,134 | N/A | 7.2 | N/A | 4.6 | 3.7 |
| Recreational Therapists | 7,292 | 6,898 | 7,273 | -5.4 | 5.4 | 5.4 | 4.3 | 3.1 |
| Respiratory Therapists | 21,860 | 23,163 | 25,300 | 6.0 | 9.2 | 6.5 | 6.7 | 4.5 |
| Respiratory Therapy Technicians | 25,303 | 26,229 | 26,424 | 3.7 | 0.7 | 4.0 | 4.2 | 3.3 |
| Medical Social Workers | 24,410 | 25,335 | 26,178 | 3.8 | 3.3 | 4.1 | 3.6 | 3.0 |
| All Other Health Prof. & Tech. Personnel | 243,040 | 230,721 | 241,734 | N/A | 4.8 | 3.6 | 3.0 | 2.8 |
| Nursing Home Personnel | 2/ | 52,070 3/ | 20,090 3/ | N/A | -61.4 3/ | 2/ | N/A | N/A |
| All Other Non-Health Professional and Non-Technical Personnel | 1,152,722 | 1,241,347 | 1,257,512 | 7.7 | 1.3 | 3.4 | 2.9 | 2.8 |
| Total Trainee Personnel | 78,229 | 81,091 | 80,110 | 3.7 | -1.2 | 1.6 | 1.5 | N/A |
| Medical Residents & Interns | 65,361 | 67,552 | 68,537 | 3.3 | 1.5 | 1.9 | 1.7 | 1.3 |
| Dental Residents & Interns | 1,411 | 1,410 | 1,379 | -0.1 | -2.2 | 0.6 | 3.8 | 1.9 |
| Other Trainees 3/ | 11,457 | 12,129 | 10,194 | 5.9 | -16.0 | N/A | N/A | N/A |

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1/ For 1980 - Included in the "All Other Health Prof. & Tech. Personnel category
2/ These personnel are included in the various individual occupation totals shown above
3/ These figures are excluded from "Total Hospital Personnel" figures
N/A - Not Available

SOURCE: American Hospital Association 1980, 1981, and 1982 Annual Survey of Hospitals.

Table 3. Average Annual Unemployment Rates for Selected Health Occupations: 1971-1983

| Occupations | 1971 | 1972 | 1973 | 1974 | 1975 | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| All Civilian Workers | 5.9 | 5.6 | 4.9 | 5.6 | 8.5 | 7.7 | 7.1 | 6.1 | 5.8 | 7.1 | 7.6 | 9.7 | 9.6 |
| Selected health occupations: | | | | | | | | | | | | | |
| Physicians (MD and DO) | 0.4 | 0.1 | 0.3 | 0.5 | 0.5 | 0.4 | 0.5 | 0.3 | 0.5 | 0.4 | 0.3 | 0.8 | 0.7 |
| Dentists | 0.5 | -- | 0.2 | 0.3 | 0.0 | 0.6 | 0.8 | 0.5 | 0.1 | 0.3 | 0.5 | 0.0 | 0.0 |
| Pharmacists | 1.1 | 0.8 | 0.4 | 1.1 | 1.9 | 1.6 | 2.2 | 1.3 | 1.7 | 1.5 | 1.7 | 2.4 | 1.2 |
| Registered nurses | 2.0 | 2.0 | 1.9 | 1.9 | 2.3 | 2.6 | 2.6 | 1.8 | 1.8 | 1.7 | 1.6 | 1.9 | 1.6 |
| Practical nurses | 3.0 | 3.6 | 3.1 | 3.8 | 4.8 | 5.2 | 3.9 | 3.4 | 4.2 | 2.9 | 3.4 | 4.1 | 5.4 |
| Nurses aides, orderlies, attendants | 6.1 | 5.7 | 6.4 | 6.2 | 8.7 | 9.3 | 8.5 | 8.3 | 7.7 | 7.2 | 9.3 | 10.1 | 10.8 |
| Therapists | 5.0 | 1.6 | 1.2 | 3.2 | 3.5 | 3.3 | 4.4 | 4.3 | 2.6 | 2.3 | 2.9 | 2.0 | 2.4 |
| Clinical laboratory technologists, technicians | 4.1 | 2.3 | 2.3 | 3.8 | 4.5 | 3.1 | 2.5 | 4.3 | 3.6 | 3.9 | 3.3 | 2.4 | 3.0 |
| Health aides, except nursing | 5.2 | 5.5 | 2.9 | 4.5 | 6.5 | 5.5 | 4.9 | 4.2 | 4.4 | 5.4 | 5.2 | 7.0 | 6.6 |
| Dental assistants | 5.0 | 3.9 | 5.2 | 6.3 | 7.0 | 8.3 | 8.7 | 5.6 | 6.3 | 6.8 | 4.9 | 5.3 | 9.6 |

Source: Unpublished data from Current Population Survey, Bureau of Labor Statistics, U.S. Department of Labor

NOTE: Occupational data for 1983 and prior years are not strictly comparable because of the introduction of the 1980 census classification system beginning in 1983.

BHPr/ODAM
3/15/84

Question: Throughout your justifications for cutting health professions you state the following: "Schools would be expected to support an increased portion of their costs from non-Federal sources." You also say that you plan to do some refocusing of health professions funds. Where are the schools going to get non-Federal financing--and what specifically do you plan to do in fiscal 1985 to refocus health professions money? How will this compare with previous years?

Answer: It is anticipated that schools will acquire funds from a variety of sources including tuition and fees, endowment and professional fee income, hospital and clinic income, State and local governments.

The Health Professions budget request directs a major effort in the area of support for the underserved and the disadvantaged and minorities. An additional $6 million above the $18 million FY 1984 appropriation for the Disadvantaged Assistance program is requested in FY 1985 to support special recruitment at health professions schools to encourage and assist the disadvantaged and minority students in increasing their opportunity for a health professions education. The budget also proposes a new Student Assistance program for the Disadvantaged for $5 million. Funds will be distributed to health professions programs with significant enrollment of students from underrepresented minority groups. A new effort under the Health Professions Special Education Initiative program for $200,000 will fund projects to develop approaches for improving the capability of already practicing health professionals to deal with the special problems of disadvantaged and minority population. The Financial Distress program is proposed for $4.2 million to continue its effort to assist four historically black colleges become financially sound and self-sufficient. In addition, a focus of funds on this priority will continue in other Health Professions programs such as AHECs, Primary Care, and Nursing Special Projects.

Overall, approximately two-thirds ($70 million) of the FY 1985 health professions budget will address barriers which make access to health professions education difficult for underserved and underrepresented groups. In FY 1983 and FY 1984, approximately $90 million was available to address these same concerns.

## PRIMARY CARE

Question: You are proposing major cuts in the various primary care programs, including family medicine residencies and general internal medicine. Since primary care is the front line of medicine and can help us with cost containment, why would you make such big cuts?

Answer: It is in light of overall funding constraints that the budget proposes focusing available health education funds on the most pressing problems of quality and distribution. To do this, the budget is focused first and foremost on a set of related and overarching issues:

(1) Increasing opportunities in health education for the economically disadvantaged and minorities; and

(2) Increasing the numbers of health care providers serving populations of minorities and underserved.

Question: What are the continuation costs for the programs in Family Medicine and General Internal Medicine and Pediatrics?

Answer: We estimate the FY 1985 continuations cost for the Family Medicine Residencies program to be $29,071,000 and $15,414,000 for the General Internal Medicine and Pediatrics program.

Question: In fiscal 1984 about $1.9 million of the appropriation for Family Medicine went for dental residencies. How much is included in your request for this purpose in FY 1985?

Answer: No funds are included in the FY 1985 budget for the General Dentistry Residencies and Training program.

Question: Will the country have enough dentists in, say, 1990, or are we looking at a possible shortage?

Answer: It is expected that the supply and requirements for dentists to be almost in balance through the end of the decade. While it appears that the Nation's supply will be adequate, problems of dentist maldistribution are likely to remain.

## DISADVANTAGED ASSISTANCE

Question: While you are cutting millions from health professions programs, you are requesting $5 million for a new program called "Student Assistance for the Disadvantaged." What sort of program do you have in mind, and have you sent up the new legislation?

Answer: The student assistance for the disadvantaged program would provide through the Health Professions Student Loan program long-term, low interest loans for medical, dental, veterinary medicine, optometry, podiatry and pharmacy students in health professions schools. One-half the amount appropriated would be allocated to schools with at least 50 percent underrepresented minority enrollment and one-half allocated to schools with 10 to 49 percent underrepresented minority enrollment.

Legislative proposals have been drafted and at this time are being reviewed by the Department and OMB. We expect them to be ready soon for submission to Congress.

Question: How will this program differ from other existing programs to meet shortages in the health professions field?

Answer: Funds requested in support of the student assistance for the disadvantaged program would be targeted specifically for minority students by allocating a greater proportion of appropriated funds to schools with large minority enrollment. Thus, students in these schools will have increased access to long term, low interest loans.

Question: Why can't existing health professions programs be tailored to deal with under-representation of minorities in the field?

Answer: Currently, funds appropriated in support of the Health Professions Student Loan program are allocated to all health professions programs by statutory formula. All students with financial need are eligible to apply for funds respective of minority status. Therefore, appropriated funds are not specifically targeted at schools with significant numbers of minority students.

Question: What do you intend to do with the additional $5.8 million you have requested for the Disadvantaged Assistance program? How does this relate to the proposed program called: "Student Assistance for the Disadvantaged"?

Answer: The increase of approximately $6 million would permit the funding of about 35 new awards. It will provide support for demonstration projects to develop health careers pathway model programs providing for continuity of support as students progress through the educational ladder. It will also provide support for projects that will be used to determine the most efficient and cost effective use of academic support and tutoring activities which are beneficial to disadvantaged students throughout the educational program.

The Disadvantaged Assistance Program is institutional rather than student oriented. It provides funds, through grants or contacts, to health professions institutions and other health and educational entities to assist minority and other disadvantaged students to enter and complete health professional education. This assistance comes in many forms including programs in test-taking and study skills, review courses in a wide range of academic subject matter, counselling, etc. The Disadvantaged Assistance program funds cannot be used to pay tuition or costs associated with academic credit.

Student Assistance for the Disadvantaged is a loan program. Funds will be distributed to health professions institutions participating in the HPSL which enroll high concentrations of minority students. These funds are used by students in direct support of their academic expenses.

## HEALTH PLANNING

Question: Once again you are proposing to terminate the Health Planning program despite the fact Congress is keeping it alive pending approval of further authorization for the activity. Much of the legislative controversy centers around how stringent the so-called "Certificate of Need" requirements should be. How effective are current certificate of need requirements in holding down spending on health facilities and equipment?

Answer: According to our information, from 1979 to 1982, States reviewed over 26,000 Certificate of Need (CON) applications for capital expenditures totalling more than $47 billion. Nearly 3,000 of those applications, totalling $9.6 billion, were disapproved by State CON agencies as unneeded. These disapprovals, in this 4-year period, account for about 11 percent of all applications and 20 percent of the proposed dollar expenditures.

While the CON system may have led to denials of unnecessary expenditures, the program creates what the Administration views as an unnecessary regulatory burden. The "free market" approach to health planning is considered more desirable.

In addition, if you were to apply a rule of thumb that a typical dollar of capital expenditure leads to 30 cents in annual operating costs, the CON disapprovals in 1979-82 saved over $2.8 billion in additional annual operating costs. Projected 10 years, this is a saved total of $28 billion in operating costs above the disapproved $9.6 billion in capital expenditures.

Question: We understand that several states still do not have certificate of need laws and that many state laws on the subject do not meet your requirements. What can you tell us about this?

Answer: Currently, three States and the Virgin Islands do not have CON laws. Louisiana and the Virgin Islands never enacted a CON law. Idaho and New Mexico allowed their laws to expire in June 1983. However, the three States and the Virgin Islands do administer a capital expenditure review program under Section 1122 of the Social Security Act. Louisiana has administered an 1122 program since 1973 and the Virgin Islands has administered an 1122 program since 1978. Idaho entered into an 1122 agreement with the Department in July 1983 after its CON legislation expired. New Mexico administered both an 1122 review program and a CON program until June 1983. It continues to operate an 1122 program.

Although forty-seven States, the District of Columbia and Puerto Rico have CON laws, twenty-six of these laws do not comply with current Federal requirements. The reasons for non-compliance generally involve thresholds, inadequate review procedures and criteria, inadequate scope of coverage, and HMO requirements.

Question: Assuming Congress decides to continue the Health Planning program, what are your fiscal 1985 continuation requirements for funding and staff positions?

Answer: To maintain the Health Planning program at current levels, we would need $58,256,000 for program activities, which is the same as the FY 1984 level, and the restoration of $8,585,000 and 130 positions for Direct Operations above the President's FY 1985 budget request.

## UNOBLIGATED FUNDS

Question: The Subcommittee understands that you may have as much as $13.5 million in unobligated funds available to you from prior years. How did you mange to accumulate these unused amounts -- and over what period of time?

Answer: These funds were accumulated from two sources, unused funds provided for the Meharry Loan Repayment and recoveries from facilities construction accounts. All but $1.3 million were recovered in fiscal year 1983. The construction recovery was the result of a one time concerted review of the accounts.

Question: What do you plan to do with the unobligated funds in this and future years? What action would be required of the Committee?

Answer: We do not anticipate that future recoveries of funds will accumulate in totals anything like the $13.5 million. The FY 1983 experience resulted from special circumstances. Any funds recovered would be proposed for use for future needs as circumstances dictate but they would have to be reappropriated by Congress. In FY 1984, we are proposing that most of this balance be used to meet pay raise costs, as follows:

| | FY 1984 Pay Costs |
|---|---|
| Health Resources and Services Administration | $ 3,270,000 |
| Indian Health Service | 6,904,000 |
| Food and Drug Administration | 627,000 |
| Fogarty International Center, NIH | 71,000 |
| National Library of Medicine, NIH | 607,000 |
| Office of the Director, NIH | 616,000 |
| Office of the Inspector General | 1,474,000 |
| Total | $13,569,000 |

Question: The Subcommittee notes that almost half of the unobligated funds -- $6.1 million -- is left over from the $29 million Congress agreed to provide for paying off a loan to Meharry Medical College in Nashville, Tennessee. Was the $29 million simply a bad estimate by the Department?

Answer: At the time that the Congress appropriated $29 million for the repayment of the Meharry loan, the repayment mechanism was still under negotiation. The appropriation estimate was based on the $29 million face amount of the original loan guarantee to Meharry.

Question: The Subcommittee is aware that you periodically make recoveries of funds from construction activities where, for example, estimates of need change. What is your estimate of recoveries for FY 1984 and 1985?

Answer: At the end of February 1984, we have recaptured $83,000 but had obligated $242,000 for prior year construction grants for a net change of -$159,000 in unobligated funds. We do not expect this net change to vary significantly as a result of close out of prior year construction grants in FY 1984 and FY 1985.

## MCH BLOCK GRANT

Question: For the Maternal and Child Health Block Grant, the law requires the States to meet several reporting requirements and yet we come away from your justification knowing precious little about the functioning of this vital program. What is the problem here? Are the States not complying with the reporting requirements of the law -- or are these requirements inadequate to the task?

For example: Have the States eliminated or reduced any services for mothers and children as the result of the creation of the Block? What percentage of State funds are spent on traditional MCH services such as well child clinics -- and how much is spent on newer activities such as prevention of lead-based paint poisoning?

What changes could be made to current data reporting requirements to improve everyone's ability to understand and evaluate what's going on in the MCH Block?

Haven't you already done some special data collection on lead-based paint poisoning prevention?

Answer: The law requires that the States report to the Secretary on activities supported with each year's Maternal and Child Health block grant funds. States have been complying with this requirement. Because State programs differ significantly in terms of the types of services and priority areas they address, the Department did not build in specific rigorous reporting requirements in the regulations governing block grants. However, we have provided States with a suggested format for the block annual report and most utilized this in preparing their FY 1982 report. We provided this same format to States for their FY 1983 submission (format attached). A report on State activities is being prepared in accord with the Section 509(b)(1) requirement and will be submitted to the Congress.

The GAO recently completed a 13 State study focussed on the implementation of the MCH block grant program. We understand that, at the final draft stage, their conclusions are that States have maintained most service programs and have increased the amount of non-Federal resources above the level utilized prior to the block. Some formerly categorical programs such as the lead activity experienced some decrease in funding support with the advent of the block. This did not necessarily mean that lead screening services decrease on a Statewide basis. A special report indicates that lead screening activities reported by the Association of State and Territorial Health Officers (ASTHO) reporting systems carried out by States in 1982 are in excess of those under the previous 1981 categorical activities administered by CDC as a project grant activity.

States are not required to identify funding levels for specific traditional versus newer activities so we are unable to respond to your question in this regard.

One of the key elements of the block grant is its emphasis on the reduction of reporting burden on the States and the concomitant freeing of funds previously used for such administrative purposes for use in payment for services. It is hoped that studies such as that by GAO along with the Special Projects of Regional and National Significance (SPRANS) report and the cited State activities report will provide necessary information on the Maternal and Child Health Services Block Grant. We do not feel, therefore, that the State data reporting requirements should be increased.

March 1, 1984

## FOR USE BY STATE AGENCIES IN DEVELOPING THEIR 1983 MATERNAL AND CHILD HEALTH BLOCK GRANT ANNUAL REPORTS

(Outline of PHS Report to Congress (Proposed Subject Areas))

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## IF CONGRESS VOTES "NO"

Question: One of your proposals is to expand the Primary Care Block Grant to include Family Planning, Migrant Health and Black Lung Clinics. You also propose to eliminate the 15 persent set-aside in the MCH Block Grant. If Congress votes "No" on your proposals, how much will you need -- in additional dollars and positions -- to operate at the current services level for the programs involved?

Answer: The 1985 expanded Primary Care Block Grant request of $533,400,000 provides an inflationary increase of 2.2 percent over the 1984 level. If the block grant proposal is not approved, the distribution of the 1985 request would be as follows:

| | 1984 Appropriation | 1985 Request |
|---|---|---|
| Primary Care Block Grant/ Community Health Centers | $377,000,000 | $344,200,000 |
| Black Lung Clinics | 3,120,000 | 3,195,000 |
| Migrant Health | 42,000,000 | 42,925,000 |
| Family Planning | --- 1/ | --- 1/ |
| Total, Primary Care Categorical Programs | $382,120,000 | $390,320,000 |

1/ Excludes $140,000 in 1984 and $143,080,000 in 1985 for the Family Planning program which has been transferred to the Office of the Assistant Secretary for Health.

An additional $19,235,000 and 379 positions would be required to operate the programs within the Bureau of Health Care Delivery and Assistance (BHCDA) at the FY 1985 current services level. A breakout of the total amount is as follows:

Direct Operations Resources Required to Continue Administration of BHCDA Programs at Current Services Level in Fiscal Year 1985

| | Positions | Amount |
|---|---|---|
| BHCDA Direct Operations | | |
| Existing 1985 President's Budget | 334 | $20,793,000 |
| To restore management of categorical programs in 1985 | +379 1/ | +19,235,000 1/ |
| 1985 Current Services | 713 1/ | $40,028,000 1/ |
| Program Management | | |
| Existing 1985 President's Budget | 154 | $ 8,025,000 |
| To restore overall agency management of programs | +63 | +7,199,000 |
| 1985 Current Services | 217 | $15,224,000 |

1/ Excludes 66 positions and $3,621,000 for Family Planning which would be in OASH restoration.

Question: How much will be needed over and above your request in the Office of the Administrator for program management?

Answer: The estimated amount over the FY 1985 Administration's request to restore program management to the current services level is $7,199,000. The total FY 1985 current services level is as follows:

| | Positions | Amount |
|---|---|---|
| Program Management | | |
| Existing 1985 President's Budget | 154 | $ 8,025,000 |
| To restore overall agency management of programs | +63 | +7,199,000 |
| 1985 Current Services | 217 | $15,224,000 |

## NATIONAL HEALTH SERVICE CORPS

Question: We know you need accurate and current data on Health Manpower shortage areas to assist you in assigning corps doctors. To what extent do you control your appetite for information so as not to impose impossible paperwork burdens on local government?

Answer: The NHSC utilizes information that is currently available on Health Manpower Shortage Areas through National organizations and government agencies. When additional information is required, only the appropriate State and/or local health planning agencies are contacted for specific areas in question. These areas usually involve a request to place a health professional in a community or retain one in the area. The NHSC does not request additional information on a general information basis.

## NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP DEFAULTS

Question: Last year we asked you about those who have received National Health Service Corps scholarships but have defaulted on their contractual obligation to serve in the corps. At the time it appeared that perhaps as much as $36 million was owed the Federal government from defaults or breaches of contract. You told us in the hearing that you were "fairly optimistic" that over a reasonable period of time you would collect the bulk of the money "because we are certainly going to be very aggressive about getting it." What progress are you making?

Answer: We have made significant progress in intensifying our collection activities. In FY 1983, we collected about $4 million, but in FY 1984 we expect to collect $5.6 million, an increase of 35 percent and in the first quarter of FY 1984 we collected more than $1.7 million. Nonetheless, the total amount owed to the government by scholarship recipients has continued to increase as there are now more recipients who must pay the triple penalty breaching their contracts.

Question: You said there were some 177 practitioners who owe an average of $57,910 because they are under a newer program and face triple penalties for breach of contract. Are any of the 177 in repayment? Are you taking anybody to court over this problem?

Answer: Yes, there are a few of the 177 who are in repayment status. Another portion of the 177 have changed their minds and decided to provide service in shortage areas. Those who refuse to enter into a repayment agreement or to provide service are definitely being referred to the Department of Justice for litigation.

## STUDENT LOANS

Question: The Department originally had proposed that schools with a better than 5 percent delinquency rate in Health Professions Student Loans be cut off from these funds. However, we understand that implementation of the cut-off has been delayed until the end of this year. Please bring us up to date on this matter. Why wasn't the cut-off put into effect as planned, and how many schools currently are about the 5 percent limit and on the delinquency list? How many are on probation?

Answer: The Department has received numerous comments regarding the equity of the new Health Professions Student Loan Regulations. The Secretary does not wish to impose severe penalties on the schools until all comments have been fully evaluated. A particular area in which a high level of concern has been expressed is in the calculation of the delinquency formulas.

Based on data as of June 30, 1983, 123 health professions programs had a borrower or dollar delinquency rate exceeding 5 percent. These programs were placed on probation in accordance with regulations in effect at that time.

Currently, no schools are on probation since the Secretary delayed the implementation of the performance standard requirements until December 31, 1984.

Question: What's your estimate of the number of needy students who would be deprived of Health Professions Student Loans if the 5 percent limit were put into effect today? Next December 31?

Answer: We estimate that at least 74 of the 312 health professions programs would have been suspended as of December 31, 1983 had the regulation implementation not been delayed for one year. Approximately 5,200 needy students in these health professions programs would not have been eligible for a health professions student loan.

We are unable to project at this time the number of programs that would be affected as of December 31, 1984. However, we assume that there will be a decrease in the number of schools affected when the new regulations go into effect as schools are continuing to improve their loan collection efforts.

Question: We understand that the Office of Inspector General has identified 1,500 Federal employees as holding delinquent Health Professions and Nursing Student Loans. What's the total value of these loans and what are you doing to get the government's money back? How many HHS staff, if any, are among the delinquents?

Answer: The total value of these delinquent loans is approximately $800,000 in combined principal and interest.

There are 21 Federal agencies that employ over 700 employees that are currently in delinquent status. We have verified the current delinquencies of these individuals. Letters requesting the cooperation of the Personnel Offices in contacting their employees who are delinquent in payments have been forwarded to the 21 agency heads from the Office of the Assistant Secretary for Health. We are now monitoring the efforts of the agencies and providing assistance when needed.

Of the 188 DHHS delinquent employees, 140 have established repayment schedules, 34 employees have terminated government service and the remaining 14 employees are still being counseled and remain delinquent as of April 1, 1984.

## NURSING RESEARCH

Question: The Institute of Medicine Study of Nursing recommended the creating of a center for nursing research somewhere in HHS. As you know, the House version of the NIH reauthorization bill provides for a National Institute on Nursing at NIH. What is the Administration view of the Nursing Institute proposal contained in the House bill? What would happen to the nursing research program we fund under this account if a Nursing Institute were created? If a Center for Nursing Research is needed, why not establish one in the Health Resources and Services Administration? How do the costs of establishing an institute compare with the costs of establishing a center in your agency?

Answer: As Dr. Brandt stated on March 14 in his testimony before the Senate Labor and Human Resources Committee, the Public Health Service (PHS) is opposed to the creation of an Institute for Nursing Research at the National Institutes of Health. We are considering several other approaches to strengthen nursing research in PHS and assess an appropriate organizational locus for such a program within the intext of existing PHS resources.

## SPECIAL EDUCATION INITIATIVES

Question: The Subcommittee notes that you are requesting level funding for Special Education Initiatives which is designed to help the health community deal with emerging problems such as the need for more doctors with geriatric training. To what extent is the $3 million funding level you propose a cutback in this program? For example, we note that just holding the program at current services would cost an additional $159,000.

Answer: The proposed $3 million funding level for this program will provide for the continuation of ongoing programs at a slightly reduced rate. This will allow funding for a modest new initiative to develop approaches for improving the capability of already practicing health professionals to deal with the special health problems of minority and disadvantaged populations.

Question: You're spending almost $1 million on geriatric training projects, but we've heard that you could profitably put $3 million into this area. What's your comment?

Answer: Four geriatric education centers were established in October 1983 at the University of Southern California, the Harvard Medical School, the University of Michigan, and the State University of New York at Buffalo. Each serves a defined geographical area with the objective of better preparing health professionals to deal with the health needs of elderly persons. The establishment of additional geriatric education centers would extend the provision of services beyond the 11 States that can be reached by the four centers established last October.

Question: To what extent are the curricula of our nation's medical schools adequate to meet the future need for physicians trained in geriatric medicine?

Answer: There is general agreement among health professionals that the curricula of medical schools are not adequate to meet the future need for physicians trained in geriatric medicine. More attention needs to be directed towards undergraduate medical education and in selected postgraduate programs which prepare medical students to treat health problems unique to an aging population. Such an effort will be possible if faculty highly trained in appropriate specialties are available to prepare future physicians to meet the health needs of geriatric patients.

Question: What level of support should be considered in developing or expanding instruction in geriatric medicine?

Answer: At the direction of the House Appropriations Committee, a Report to Congress on Education and Training in Geriatrics and Gerontology was recently prepared by the Department and submitted to Congress on February 28, 1984. One of the five objectives outlined in the report is to expand and integrate geriatrics and gerontology in basic health professional education programs. Under Sec. 788(b) of the Public Health Service Act, in October 1983, the Bureau of Health Professions established four regional geriatric education centers for the training of multi-disciplinary faculty (including medicine, dentistry, nursing and social work, along with other discipiines such as pharmacy, occupational and physical therapy and clinical phychology), the development of geriatric curricula and continuing education materials, and to serve as geriatric information resource centers within their designated geographic areas.

HANSEN'S DISEASE CENTER

Question: The Subcommittee notes that you once again are trying to reduce the special pay that is provided for employees at the National Hansen's Disease Center in Carville, Louisiana. I've never understood why you keep trying to do this, given the difficulty of maintaining the best possible staff at this remote but important site. What is your rationale?

Answer: The rationale behind the attempts of several administrations to do away with special pay for NHDC employees is based on the fact that Hansen's disease (HD) presents no particular threat to the employees at the center. Since the PHS assumed responsibility for the facility in 1921, not one employee has been diagnosed as having the disease. The major hurdle of patients with HD is the stigma associated with leprosy. The continuation of special pay to work with the patients supports the stigma by suggesting an uncleanliness and danger which is simply not true.

The staff at the NHDC are professional and dedicated to the performance of high quality clinical care, research and training. Any reduction in the special pay would be expected to have some affect on recruitment of new personnel; however, continuing to provide special pay for an imaginary threat is inappropriate.

Question: How successful have your regional centers been in bringing Hansen's Disease patients in for treatment? Why is your patient load at Carville going down?

| Answer: | FY 1982 | FY 1983 |
|---|---|---|
| Outpatient Visits | 2,703 | 2,300 |
| # patients under treatment | 824 | 842 |
| Admissions | 61 | 60 |
| In-patient Days | 612 | 719 |

While FY 1983 was primarily devoted to developing the Regional HD Center Program, a review of the statistics provided below would indicate that this approach has proven to be successful. The figures below for FY 1982 and FY 1983 are limited to the 7 Regional

HD Centers that were existing during FY 1982 and FY 1983, namely, Boston, Staten Island, Miami, San Diego, Los Angeles, San Francisco, and Seattle. Other sites which were added to the program late in FY 1983, include Hawaii and Phoenix. The statistics for FY 1984 reflect the addition of these sites.

|  | Actual FY 1982 | Actual FY 1983 | Estimate FY 1984 |
|---|---|---|---|
| Out-patient visits | 2,703 | 2,300 | 5,300 |
| # patients under treatment | 824 | 842 | 1,518 |
| Admissions | 61 | 60 | 64 |
| In-patient days | 612 | 719 | 767 |

The national policy of treating individuals with HD in their local community through a network of Regional HD Centers will continue to grow, creating a corresponding decrease in the number of long term care patients at the NHDC. Since the implementation of Regional HD Centers, the program has been widely accepted and highly successful.

Question: Tell us about the interesting rehabilitation research work that is underway at Carville. How is it progressing and do you share your findings with other government agencies as well as with related groups in the private sector?

Answer: The Rehabilitation Research Department of the National Hansen's Disease Center is involved in a number of projects related to the neuromuscular and musculoskeletal systems.

One of our major research projects is the Surgical Workstation. It will be an easy to use computer that will allow a surgeon or other medical professionals to see a realistic representation of their patient's hand or foot on a television screen. The surgeon could then see the functional results of surgery before performing the procedure. For example, a patient with a nerve injury often requires surgery to transfer muscles and tendons in the hope of regaining lost function. The surgical Workstation would allow the surgeon to try out an infinite number of possible combinations, and come up with the best procedure for his patient.

This five year project was begun in September 1983, and is on schedule. We now have a "real time" model of the thumb that allows us to do simple tendon transfer and see the results.

The primary audience for the Surgical Workstation will be surgeons, therapists, and students. It will be used for planning therapeutic management and for training. In five years this project will be completed, and the Surgical Workstation will be made available to hospitals, clinics, private practitioners, and training institutions in the U.S. and around the world.

Even with the brief experience we have had so far in developing the Surgical Workstation, we recognize that the ultimate utilization of the system will depend on an electronic communication network. That is, tieing in the medical community ("users") to one giant expert system at the NHDC.

We propose, in the next two years, to develop a comprehensive, user-friendly communication network that will be the first step in making the NHDC a national and international center for hand and foot surgery and biomechanics. We hope to obtain the necessary equipment this year.

The National Hansen's Disease Center has long been recognized as the primary center for the development and evaluation of custom orthopedic footwear. We have just completed a study of he effect of some of these shoe modifications on pressure against the foot.

We are currently discussing with NASA and the VA the feasibility of a cooperative study using NASA's shape sensing technology as a means of evaluating deformed feet. This would be a significant advance in helping provide good footwear for people now crippled by severe deformities.

Shoemaking is a labor intensive process. This cooperative effort could potentially cut the cost of custom made shoes to the wearer by 80 percent. This would be a considerable savings in health care costs around the country and make custom shoes available to broad segments of our society. In the past, many patients have had amputations and have been confined to a wheelchair because of the limited availability of custom made shoes.

Our ability to measure sensory and motor function in patients has now reached a level of sophistication that allows us to begin working on another major project. We are starting a research project this year that we hope will lead to our being able to prevent or reverse the sensory and motor loss in HD. Peripheral nerve involvement (which results in sensory and motor loss), is responsible for deformity in HD, yet a standardized test battery shown to sensitively demonstrate early changes of the peripheral nerves has yet to be established. A research project is being launched to investigate the use of a test battery which has clinically demonstrated sensitive changes in peripheral nerve status. This test battery is being developed to monitor the course of peripheral nerve involvement so that changes can be interrupted before irrepairable loss of nerve function has occurred.

It is intended that the test battery being investigated will be used in subsequent planned studies to monitor the specific effect of drug and other therapies on the overall outcome of peripheral nerve status. If successful, this investigation not only has implications for treatment of HD patients, but the whole family of peripheral nerve disorders, including diabetes, and injuries to the nerves from accidents. The information immediately pertains to contract care facilities treating HD patients, to national and international health workers treating HD, to medical professionals treating diabetes patients, and to surgeons and therapists treating peripheral nerve problems.

## REAUTHORIZATIONS

Question: We note from your budget that most of your programs do not have authorizing legislation for fiscal 1985 -- and we hear that some of the needed legislative language hasn't left either the Department or OMB. What's the status of your reauthorization proposals?

Answer: The Administration's legislative proposals for reauthorization of program authorities due to expire on September 30, 1984, are in various stages of development within the Executive Branch. We expect to transmit one draft bill, the "Health Services Amendments of 1984," to he Congress in the very near future. Two other proposals--on Health Professions/Nurse Training and on Health Maintenance Organizations--are under development.

## COMMUNITY HEALTH CENTERS

Question: I'm intrigued by some of the things you're trying to do in the Community Health Center program. I note you are trying to expand State involvement in program funding decisions-- and that about 40 States have agreed to participate in the decision making process. Has this resulted in better execution of the program, better location of centers, etc.?

Answer: We believe that increased State involvement in primary care program operation is critical. Over the past several years, the Bureau of Health Care Delivery and Assistance has developed cooperative Memoranda of Agreement (MOA) with over 40 states. Our experience with the MOA's has been extremely positive. State input in program planning, targeting of resources, and individual community needs has been invaluable.

Question: You also refer to the provision of services to persons in 40 "high need" communities. Where are these communities and how do they differ from other community health projects?

Answer: The 40 high need projects have yet to be identified. We have entered in to a process of first determining the areas of greatest need and then secondly encouraging the development of applications to serve those areas.

We are working closely with the States in determining areas. We asked for their cooperation in this venture in letters to the Governors in December. Our regional offices now are following up and developing data on the extent of poverty, the comparative shortage of physicians, the unemployment rate and the extent of State support for each area.

We shall have a list of the areas of greatest need completed within the next few weeks and our regional offices, in many cases working closely with States, will proceed to initiate the development of applications from well managed potential grantees.

From these applications and any unsolicited applications which maybe submitted unsolicited, we shall choose the final group of 25 to 40 successful projects.

## CARES PROJECT

Question: In our fiscal 1984 report, we directed that the CARES project in North Dakota be funded by your agency through the Community Health Centers program. We understand CARES has been refunded, and we do appreciate that, but we still have several questions. How much was made available for CARES in the new fiscal year and what plans do you have for continuing its funding in fiscal 1985?

Answer: We have made available $187,955 for CARES in FY 1984. The funding level is for a 12 month period January 1-December 31, 1984. We have proposed that both sources of funding for CARES be included in block grants in 1985. In that event future funding would be up to North Dakota. Should these funds remain categorical we do intend to fund CARES in FY 1985.

Question: Why is a portion of the CARES project being funded under the special set-aside in he MCH Block Grant instead of providing all of the money under the Community Health Centers program?

Answer: We are funding CARES partially under the special set-aside in the MCH block grant because CARES is a project with an emphasis on both pediatric and adult rehabilitation as well as primary care.

Question: What is the effect of this split-funding approach -- and is there any danger in doing it that way? For example, what would happen to CARES if your proposal to eliminate the MCH special set-aside is approved?

Answer: There is no affect of split funding upon CARES. Cares still operates as if it were funded from a single source. Any future danger to CARES in split funding would assume that the State of North Dakota would not support it. For example, under the proposed Maternal and Child Health Block Grant the MCH special set aside would be eliminated. North Dakota would have the option of using the extra money form its share of the special set-aside, in addition to other funds that may be provided, to assist in funding the CARES project.

## HOME HEALTH

Question: Your justification material for the Home Health program provides no information as to how the $5 million appropriation for fiscal 1984 was or is being used. What have you done with the money?

Answer: We divided the 1984 appropriation of $5 million into $4 million for the development and expansion of home health agencies and $1 million for grants to train homemaker home health aides. We expect to make about 69 grants and loans for agencies with the $4 million and to train about 3,000 homemaker home health aides with the $1 million.

Question: What's the impact of your proposal to terminate the program in fiscal 1985 since you've requested no additional funds?

Answer: The impact of not including Home Health in the 1985 budget should be minimal. The training programs are short term and will be completed. The grants and loans are for new development and expansion only. In almost all instances these should be able to be continued without further assistance. States also have authority to provide such assistance under the Preventive Health Block Grant.

Question: How do you distinguish these home health funds from home health money you make available to the program under Medicare and Medicaid?

Answer: Funds authorized under section 339 of the Public Health Service Act are for the award of grants to support initial costs of establishing or expanding home health services and to train paraprofessionals, including homemaker home health aides, to provide home health services.

Medicare, Medicaid and the party payors cover reimbursement of some health care services and other medical supplies provided by Medicare and Medicaid home health care agencies.

## HEALTH MANPOWER SHORTAGE AREAS

Question: The Subcommittee is increasingly concerned about the availability of Federally-supported health professionals to underserved areas. This is now particularly important since you want to cut off National Health Service Corps scholarships that are used to educate future physicians. To what extent will there always be health manpower shortage areas that will require placement of Corps doctors and other health professionals?

Answer: Targeted primary care training and service programs, including the National Health Service Corps (NHSC), and the geographic diffusion of health personnel resulting from private sector market forces are working to reduce the number of health personnel needed in health manpower shortage areas. However, there will always be some health manpower shortage areas which do not benefit from the interaction of these programs and market forces.

Question: How can we be assured that the Corps will have sufficient trained personnel to place in shortage areas which may never be able to attract and retain doctors?

Answer: The NHSC is proposing to supplement and eventually replace the scholarship pipeline with a volunteer program which offers incentives to health professionals willing to serve in Health Manpower Shortage Areas.

Question: How many National Health Service Corps sites do you expect to have a year from now -- and five years from now?

Answer: In 1985, we expect to have NHSC field staff placed in 2,050 sites. In 1990, the number of sites will be reduced to about 600.

## FEDERAL EMPLOYEE HEALTH

Question: The Subcommittee notes that you are proposing two changes in your authority to operate Federal employee health units, and that you are requesting no funding for the program in fiscal 1985. Are you saying that your authority to "operate" these health units isn't sufficient -- and that you also need to add the word "administer" to the statute? Please explain.

Answer: The Division of Federal Employee Occupational Health manages and administers a system of employee health programs for a number of Federal agencies all over the country. The costs of managing and administering the system are not now being fully covered in the reimbursements that the Division receives from the agencies; some of the costs are covered by the direct appropriation. The 1985 budget request that the reimbursement received from each agency cover the costs not only of the specific program operated for that agency but also for a proportional share of managing and administering the system. The word "administer" was added to the proposed appropriation language to ensure that it would be clear that this overhead aspect would be included among the costs for which an agency would be billed.

Question: The existing law provides for reimbursements or advances to cover payment for the "estimated cost" of operating the health units. You propose to make the authority read "full estimated cost," adding the work "full." Why?

Answer: The costs of managing and administering the system are not now being fully covered in the reimbursements that the Division receives from the agencies; some of the costs are covered by the direct appropriation. The 1985 budget request proposes that the reimbursement received from each agency cover the costs not only of the specific program operated for that agency, but also for a proportional share of managing and administering the system. Agencies will be billed for the full costs, including overhead costs, of operating the employee health program.

Question: Why are you requesting no funds for the Federal Employee Health program in fiscal 1985? (Note: The program received an appropriation of $1.2 million for fiscal 1984.)

Answer: The program will be funded on a reimbursable basis in 1985.

## HEALTH PROFESSIONS STUDENT LOANS

Question: The Subcommittee notes that some $49 million in revolving funds are available for Health Professions Student Loans in fiscal 1985. Small wonder that you aren't asking for new appropriations for the program. Yet, I wonder whether even this amount meets the universe of need for such loans among students from low-income families. What can you tell us?

Answer: We feel that with the $49 million in the Health Professions Student Loan Revolving Fund and funds from the Department of Education, as well as funds from State and school programs, there will be adequate resources to meet the needs of students from low-income families. In addition, we are requesting $5 million in student loans for schools with significant numbers of minority and disadvantaged students.

Question: Is the $49 million all that you have in the revolving fund -- or is that just the amount that you are budgeting for further loans out of that pool of paid-back loan receipts? In other words, is more available?

Answer: The $49 million projected as available in FY 1985 in the health professions revolving funds is based on collections (paid-back loan receipts) and "cash-on-hand" as reported by the institutions on their latest annual operating reports. Funds from other sources are not anticipated in FY 1985 for these revolving funds.

## NURSE ANESTHETISTS

Question: Congress provided $400,000 to initiate the Nurse Anesthetist program in fiscal 1984, but I notice that you request no further funding for this activity. Why do you want to terminate this program -- and what are the "higher priority programs" you propose to use this money for in the new fiscal year?

Answer: The higher priority programs in the Administration wishes to fund are those preparing nurses for responsibilities which address national health care goals, such as preparing practitioners for primary health care settings and expert clinicians, teachers, and administrators in such areas as community health, maternal and child health, geriatrics and acute care.

Question: Your justification states that you plan to distribute the fiscal 1984 money to 24 institutions in support of 72 trainees. Has the money gone out yet -- and what will happen to the programs that are funded if the money is cut off after one year?

Answer: Institutions are now completing their applications and awards will be made in July 1984. Termination of programs will not affect recipients of traineeships funded in FY 1984 since awards are being made only to students in their final year of their program of study.

## PHYSICIANS ASSISTANTS

Question: You propose to kill the Physicians Assistants program for which Congress appropriated almost $5 million in fiscal 1984. What could be your rationale for this -- particularly when your own justification says that the delivery of health care in shortage areas "has significantly increased as a result of the Federally funded Physician Assistant program?"

Answer: Current projections indicate that the number of physician assistants (PAs) will increase to an all-time high of 22,100 by 1990. The Federal Government is recommending restricting Federal support in funding physician assistant programs in order to direct Federal resources to higher priority needs.

Question: To what extent has the presence of physicians assistants led to removal of shortage area designations throughout the country?

Answer: The criteria for designation of primary medical care health manpower shortage areas (HMSAs) take into account both allopathic and osteophahic physicians but does not take into account physicians assistants or nurse-practitioners. Therefore, the presence of physicians assistants does not lead to removal of shortage area designations. The Rural Health Clinic Services Act (P.L. 95-210) allowed for Medicaid/Medicare reimbursements of physicians assistants and nurse-practitioners only in those rural health clinics located in HMSAs or MUAs (medically underserved areas). Consequently, it was viewed as counterproductive to possibly remove such areas from the HMSA list by counting these practitioners since that would preclude their reimbursement and likely contribute to their leaving the areas involved.

## AREA HEALTH EDUCATION CENTERS

Question: You continue to cite evaluative studies that show that the Area Health Education Centers program "has had a significant positive impact." Yet we find that your budget proposes to reduce the program by almost $8 million below the $18 million provided in the current fiscal year. Please explain why your actions belie your words about this program.

Answer: The projected reduction in AHEC programmatic activity and dollars is principally related to controlling overall Federal expenditures.

Question: How much money would be required to meet continuation costs in fiscal 1985?

Answer: It is estimated that approximately $15.0 million is needed to continue AHEC activities begun in FY 1984 and prior years.

## HEALTH MAINTENANCE ORGANIZATIONS

Question: The Subcommittee notes that you continue your involvement in HMOs, but mainly to promote the concept, provide technical assistance and monitor qualified HMOs for compliance with Federal regulations. In fact the HMO concept seems to be thriving on its own. Where are we on that, and do you see even less of a Federal role in the future?

Answer: We would agree that the HMO industry is indeed thriving on its own since the termination of Federal developmental support in 1981. This is a direct result of increased private sector interest and support which has been facilitated by our efforts to encourage private financial investment in HMOs.

Although the Federal role has changed, it is no less important. Through our qualification activity and the continued monitoring of HMOs, we provide assurances to both the business community and the HMO enrollees that the qualified HMOs do meet the standards of the Federal statute and regulation. In fact, our qualification activity has increased substantially each year since 1981 and shows no sign of abating.

Question: I know that one of your jobs is to cover loan defaults by HMOs. Your justification suggests that you may request a supplemental in 1984 to cover any defaults. What you are expecting?

Answer: There were no HMO loan defaults in calendar year 1983 and, therefore, no supplemental appropriation is proposed in FY 1984.

If defaults were to occur in calendar year 1984, a supplemental appropriation request would be considered for FY 1985.

MEDICARE/MEDICAID

Question: The Subcommittee has become aware that family medicine specialists in teaching institutions may have a problem getting full reimbursement for services provided to Medicare and Medicaid beneficiaries. What can you tell us about this matter?

Answer: It is believed that primary care physicians receive lower levels of reimbursement for their services than non-primary physicians because reimbursement is significantly lower for services that are largely non-procedural, or "cognitive," in nature, than it is for procedural services. This is likely to be a particular problem for family physicians because their specialty, being entirely primary care, is largely oriented to cognitive, non-procedural care. It is also likely to provide disincentives for departments of other specialties, such as internal medicine and pediatrics, to establish primary care medical education programs because of the consequent reduction in income from faculty practice.

In addition, primary care, especially family practice, tends not to incur hospitalization to the extent of most other specialties; this results in reduced income both for the faculty and the hospital.

Many family medicine residency training programs have ambulatory care training sites that are free-standing, rather than owned or operated by a hospital. By lacking the "provider" status of being hospital based for Medicare reimbursement purposes, these sites are not eligible for cost-based reimbursement of service or training costs, and the only available income is the fees for the services of fully licensed physicians--the faculty, and residents after the first year in many States.

Question: Does it affect only residents who may be in training under government-supported programs?

Answer: Residents in training under government-supported programs are affected and do not receive full reimbursement for services provided to Medicare and Medicaid beneficiaries. All primary care training across the board is believed to be similarly affected. It is quite possible that family practice, which provides fewer procedures and fewer hospitalizations than other specialties, is the most seriously disadvantaged by the current reimbursement patterns.

Question: Have you talked to the Health Care Financing Administration about the problem -- and what is their response?

Answer: There have been a number of discussions between HRSA and the Health Care Financing Administration (HCFA) on issues of reimbursement of primary care physicians, and particularly of family physician specialists. The Administrator and Associate Administrator, HRSA, met on November 18, 1983 with the Deputy Administrator, HCFA, and staff to discuss a wide range of issues relating to HCFA and HRSA, including the Social Security Advisory Committees' recommendation to cease funding medical education under Medicare. No decisions have been made on these issues to date.

Question: Is there a differential between what Medicare pays for specialist services and what it reimburses for primary care?

Answer: It is believed that many, and perhaps most Medicare carriers, place family physicians under the "general practitioner" category of physician. However, according to informal discussions with HCFA and the American Academy of Family Physicians, there appears to be no current information on which carriers, or how many, categorize family physicians as "specialist" rather than "general practitioner." To make the subject still more intricate, some carriers are said to categorize only certain specific services as being "specialist" and others as not, according to which kind of specialist is involved. Again, there appears to be little current information available in this complex area.

## UNCOMPENSATED CARE

Question: Your justification states that you have experienced a doubling of the number of phone calls from people concerned about health facilities providing uncompensated care as they agreed to do in return for Hill-Burton funding. What's the reason for this increase in calls to your "hot line" about this matter?

Answer: The significant increase in calls to the "hot line" concerning uncompensated care was caused by an eight-line item in the May 1983 issue of Good Housekeeping in a feature entitled "Money-Gram". In that month, the number of calls tripled and remained appreciably high for the rest of the fiscal year. The number of calls in the first quarter of FY 1984 is, so far, about one and one-half times the number received in a comparable period for 1983. Subsequent publicity is probably the reason the number of calls has remained high.

Question: We understand that many nursing homes find themselves unable to comply with the uncompensated care requirements of the law. Why is this?

Answer: According to representatives of nursing homes, the regulations implementing the uncompensated services provisions of Title VI and VII of the Public Health Service Act are directed toward acute care general hospitals, and do not take into account the operational differences in long-term care facilities. These facilities claim that the major differences which impact on their ability to comply with the regulations are (1) length of stay; and (2) Medicaid reimbursement. Hospitals have the option of providing uncompensated services to patients who require only short-term treatment and can reach a large, diverse number of people. Nursing homes have no such option because many of their patients are residents for extended periods of time. Medicaid is a principal reimbursement mechanism for nursing homes. The uncompensated services regulations do not permit facilities to count toward their obligation amounts reimbursed by Medicaid or amounts which make up the difference between Medicaid reimbursement and Medicare allowable costs or usual charges. Approximately 5,000 health facilities are obligated to provide uncompensated services, of which about 3,100 are acute care general hospitals and about 450 are nursing homes.

Question: What's being done to make it possible for nursing homes to live up to the bargain they struck with the Federal government?

Answer: The Department agrees that the existing regulations were not really designed for nursing homes and fulfillment of their free-care obligation is a problem. We are willing to work closely with the Congress in reaching a resolution to this issue. We do believe, however, that any change should not result in a reduction in the amount of uncompensated care provided by the nursing homes.

## ANTI-DEFICIENCY ACT VIOLATION

Question: The Subcommittee understands that the Health Resources and Services Administration may have exceeded its authority in paying defaults from health professions guaranteed student loans. What actually happened -- and to what extent were you in violation of the Anti-deficiency Act?

Answer: The Student Loan Insurance Fund is a special account whose funds are derived solely from private capital rather than through Federal appropriations. At no time during the year were payments made in excess of available cash balances. During May of 1983, there was a technical problem in that the paperwork associated with the apportionment process did not adequately reflect the amount of funds disbursed. This was quickly cleared up as soon as it came to the Agency's attention.

Question: What have you done to correct the situation and prevent a recurrence of violations?

Answer: Specific financial management and fiscal internal controls have been put in place which require constant monitoring of this fund by the program office, the financial management office, and the office of the Bureau Director.

## FINANCIAL DISTRESS

Question: I note you are requesting $4.1 million for Financial Distress in fiscal 1985. This is a cut of $1.4 million from the current fiscal year. What is the status of the schools to which the money is made available -- and will they no longer require financial assistance after fiscal 1985?

Answer: All of the schools have been funded for the third year of their original 5-year plan although the last year of funding under this plan is fiscal 1986. Unforeseen economic and other factors, beyond the control of the schools, have hindered their progress resulting in a lag time of approximately one year. The planned increase of the State support during the second year of the plan failed to materialize due to State budget restrictions. Sponsored research has increased but not at the rate projected in the plans. Fund raising activities have been successful at some schools, but obtaining large dollar and manpower commitments to provide further gift resources have not been forthcoming due to national economic conditions. This lag in fulfilling these crucial plan elements has resulted in some increase in projected deficits, thus we believe it may take an additional year to complete the original plan objectives.

Question: Since the legislation authorizing the Financial Distress program expires this year, what new legislation are you proposing and will it extend the period of financial assistance beyond five years for any of the schools involved?

Answer: New authority may be requested for the fiscal years 1985 through 1987.

## EXCEPTIONAL FINANCIAL NEED/CORPS SCHOLARSHIPS

Question: The Exceptional Financial Need (EFN) scholarship program can help many needy students pay for their first year in medical school. Last year Congress provided $5.6 million for the program, but you request no funds for fiscal 1985. What possible reason could you give for cutting off this small amount of money that can make such a big difference in the lives of young people from low-income families?

Answer: The Administration is proposing to assist through its proposed new loan program the type of financially disadvantaged student now served through the EFN. Use of the loan mechanism allows limited funding to reach a much greater number of students. Recent data have shown that minority and disadvantaged students are at least as willing as other students to use loans to finance their medical education. By creating a special loan fund for minority institutions the schools will be able to assure that as loans are collected they can be reloaned to additional needy students without requiring additional Federal appropriations.

Question: You funded 357 students for their freshman year of medical school under the Exceptional Need program in fiscal 1984. Since you request no funds for National Health Service scholarships in FY 1985, how do you propose to help the 357 meet their future tuition costs?

Answer: Needy students attending schools with significant minority populations will be able to apply for funds under the student assistance program for the disadvantaged. Needy students will also be eligible for funds from the $49 million revolving Health Professions Student Loan fund, the Health Education Assistance Loan program, as well as programs supported by the Department of Education and State and local authorities.

## GUARANTEED LOANS

Question: Your budget requests new legislative authority to raise the premium charge on HEAL guaranteed loans to a level that will permit you to cover defaults. What is the current charge provided by law and what exactly are you proposing?

Answer: The current insurance premium permitted by law cannot exceed 2 percent. The current maximum insurance premium permitted by the regulations is 1 percent. However, a recent study by the Touche Ross accounting firm indicates that at the 1 percent premium, assuming a default rate of 8 percent (a rate found in comparable loan programs), the fund will have a negative balance in 1985. We are proposing to raise the insurance premium as soon as possible to 2 percent in order to maintain the integrity of the fund. We are also reviewing the program to strengthen due diligence and default prevention so that the default rate will be 8 percent or lower. In addition, the Administration is proposing to remove the legislative insurance "cap" to assure the long-term solvency of the insurance fund.

Question: Are you telling us that the pool of available funds to cover defaults is too small and that defaults are rising? What are the facts?

Answer: The pool is adequate to pay current default claims. However, as more students go into repayment, it is projected that the default rate which was 5.4 percent as of September 30, 1983 could rise to approximately 8 percent based on experience in other similar programs. As of September 30, 1983, 95 default claims for a total of $1.3 million had been paid. By December 31, 1983, an additional 110 claims for an additional $1.5 million had been paid. The program is now 5 years old and more students who have borrowed from HEAL program for all years of study will come into repayment status thus increasing the total potential default claims to be paid.

Answer: You should note that insurance premiums are currently made entirely as a single payment at the time the loan is disbursed. These premiums are not now set each year at a level sufficient to fund prospectively the expected defaults due to that year's group of loans. Instead, defaults each year (by prior year loan recipients) are largely defrayed by the current year insurance contributions of new loan recipients. This system has worked because there has been a constantly increasing number of new recipients in recent years. This could only be changed by substantial increases in insurance payments such that each year's class of recipients make insurance contributions sufficient to fund its own future default projections.

Question: We are told that you have authority to borrow from the Treasury to cover any shortfall in funds for defaults. Is that true -- and, if so, why not use that authority instead of trying to change the basic law in an appropriations bill?

Answer: It is true that we do have authority to borrow $2.5 million to cover shortfalls in the insurance fund. However, given the potential dollar levels which could be reached by 1985, this amount would not be sufficient to cover deficits. Total default claims paid through December 31, 1983 are approximately $2.8 million. The Administration does not desire to borrow funds from the Treasury to cover the projected shortfall. The Administration is requesting open-ended authority for determining insurance premium rates for the HEAL program in order to ensure self sufficiency and solvency of the student loan insurance fund. This fund will, therefore, contain monies acquired from actual student borrowers at time of loan disbursement to pay for defaults, deaths, bankruptcies or disabilities.

## PROGRAM MANAGEMENT

Question: The Subcommittee understands that its annual appropriation for the Program Management work of your agency goes in part to administer the Indian Health Service which is funded by the Interior appropriations bill. It would be helpful to us to know how much of the money provided for fiscal 1984 -- and how much you request for fiscal 1985 -- will be used for Indian Health Service activities. Which activities?

Answer: We estimate that approximately 17 percent of the HRSA Program Management resources are utilized to support the overall management of the IHS. In terms of funding, the 17 percent represents $2,548,000 of the FY 1984 current funding estimate of $14,986,000. If the same level of activity is assumed for FY 1985, the 17 percent represents $1,364,000 of the FY 1985 request of $8,025,000.

Program Management resources are not used to support specific IHS activities. They are used to support the overall agency management required to administer the IHS programs, among others. Such overall agency management includes management policy and program direction, program planning and evaluation, budget formulation and execution, grants and contracts management, administrative and personnel support, and equal employment opportunity.

Question: Why aren't these costs paid for from the Interior Department appropriations bill?

Answer: The annual appropriation received by the Indian Health Service (IHS) as funded by the Interior Appropriations Bill provides funds for those services and facilities as defined by the Indian Self-Determination Act, the Indian Health Care Improvement Act and various titles within the PHS Act with respect to services to be provided to the IHS.

The Direct Operations funds provided within that bill funds the operating costs for the management of the IHS. These costs include personnel services, travel and transportation, rent, utilities, and other support costs for these personnel.

Direct Operations funds provided by the Labor HHS Appropriations Bill provide operating funds for the management of the other three Bureaus of HRSA. The Office of the Administrator is supported by the Program Management funds (also provided by this bill) which provide for the overall management of the entire HRSA but not for the Direct Operations of any of its components.

Question: How much money does the Interior Department appropriations bill provide for HHS Program Management of the Indian Health Service, and is any of this used to administer programs we fund in the Labor-HHS bill?

Answer: The Interior Appropriation does not provide funding to the Health Resources and Services Administration Program Management activity to support Indian Health Service activities. However, the Interior Appropriation does provide funding specifically for the Indian Health Direct Operations activity, as well as IHS program activities.

## FAMILY PLANNING FUNDING

Question: The Subcommittee is curious as to how you are funding the Family Planning Program under your present set-up. Congress provided the appropriation to your agency but the program is directed by the Office of the Assistant Secretary for Health. Has the $140 million appropriation been transferred to the Assistant Secretary and, if so, under what authority since a transfer in this case would require a legislative enactment?

Answer: The funds for Title X and associated program support are being expended against the appropriation for the Health Resources and Services Administration (HRSA) under the direction of the Deputy Assistant Secretary for Population Affairs (DASPA).

Question: Does your agency simply act as the "Paymaster" for the program -- or do you execute a piece of paper that moves money into the Assistant Secretary's account? If paper is executed, we would like to see it. Do you have it with you?

Answer: The Health Resources and Services Administration does, in effect, act as paymaster for the family planning program.

Question: If you are simply the paymaster, how do you know to whom to send the money? How are program policies established and how are they communicated to you? Are the payment and other instructions in writing -- or do you simply respond to verbal instructions?

Answer: The funding decisions regarding allocations to the ten regional offices and determinations regarding the obligation of headquarters funds are made by the DASPA. HRSA is not involved in the program policies. The funding documents are prepared in conjunction with the Office of the Assistant Secretary for Health.

Question: How much of the $140 million appropriation has been obligated and how much do you still have in your accounts?

Answer: Initial allocations totalling $132,767,994 for service grants have been sent to the regional offices. Of the remaining $7.3 million approximately $1 million will be distributed to the regions to augment service grants. The balance of the funds will be distributed to the following program activities: family planning service delivery improvement activity; training for personnel to carry out family planning service programs; information and education activities, and evaluation activities.

## FAMILY PLANNING ISSUES

Question: The Subcommittee is concerned about efforts to dismantle a program which funds projects to improve the direct delivery of family planning services. What is the current status of the program and which current grantees are being excluded from participation?

Answer: The Services Delivery Improvement (SDI) activity is not only being continued but is being upgraded as well. The highly-respected peer review system of the National Institutes of Health was utilized for the first time to determine recipients of research grant awards. Recipients of research grants have also been required, for the first time, to deposit their data in a public use data archive, so that the data tapes would be available on a more widespread basis to all interested parties.

Several steps have been taken to bring research and practice closer together, especially in terms of input into setting a research agenda by those delivering services. Meetings were held in each region with grantees where this and other topics were discussed. Each region has been required to have a work group of family planning providers to provide input on SDI research and the Office of Family Planning has a similar group at the national level. Every effort is being made to make SDI research relevant, high quality, and available to all.

Question: What are your plans for funding the program in fiscal 1984?

Answer: Funding for the Service Delivery Improvement program in Fiscal Year 1984 is projected at $2,200,000, an increase of $600,000 over Fiscal Year 1983. New research grants will be awarded following the competitive process initiated last year which includes the NIH peer review process. Topics will be selected from those suggested by grantees and researchers as well as those identified in FY 1983. These funds will also provide continued technical assistance to grantees as well as other support activities.

Question: We understand that you've changed your contractual arrangements for collection and analysis of data regarding family planning service delivery. What assurances can you give that reliable data will continue to be made available through whatever new arrangements you make?

Answer: We are very interested in the collection and analysis of data regarding family planning service delivery in the United States. Resources within the Department have already been dedicated to gathering this information. Primary responsibility for these efforts resides in the Office of Population Affairs. Within OPA are several statisticians and demographers, including one who had major responsibility for the National Survey of Family Growth (NSFG) at the National Center for Health Statistics. The NSFG data are a major source of information on family planning services provided by private physicians and estimates of sexual activity, fecundity, and unintended pregnancies for married and single women.

A plan to collect and analyze family planning data has been developed and is under way which will utilize data from the National Survey of Family Growth Cycle III and the National Ambulatory Medical Care Survey sample of private physicians.

The results of the data activity will be available in several formats and a published report of the analysis will be disseminated. Public use tapes will be deposited in a data archive thereby making the information available to researchers, policy makers, service providers, and others interested in family planning issues.

Question: Please provide us with data which convinced you that the Family Planning Program is not providing enough services in the areas of natural family planning, infertility and male involvement.

Answer: These areas have been identified for special projects of national priority and have focused on some of the basic services that are cited in the Title X legislation. Prior to the designation of the national priority areas for 1984, meetings were held with grantees in each of the regions so that they could provide input as to which of the family planning services needed to be strengthened. The concensus that came from these meetings was the basis for the designation of natural family planning, infertility and family involvement as special projects of national priority.

## FAMILY PLANNING -- NEW TACTICS

Question: You have been aware of our opposition to moving the health block grants from their home agencies to the Office of the Assistant Secretary for Health, and you have refrained from doing so. You know of our strong opposition to moving Family Planning to the Assistant Secretary's Office, yet that is what you have done. How do you explain this inconsistency of response to Congress?

Answer: Serious consideration was given to the Congressional directive to return this program to HRSA. However, we strongly believe that the placement of the Family Planning program in the Office of the Deputy Assistant Secretary for Population Affairs in OASH is the best organizational arrangement for maintaining a strong high-quality program.

Question: Aren't you saying that your discretion to manage exceeds the authority and intent of Congress?

Answer: In the case of appropriations acts as with all other statutes, report language provides non-statutory guidance on the implementation of the statute. On those points that Congress did not include in law, the Executive Branch has considerable discretion in interpreting and implementing the guidance provided in the report language.

Question: In fiscal 1984 the Congress made clear that it wanted the Family Planning Program administered under the Health Resources and Services Administration. Why have you not complied with this directive -- why do you persist in bucking the will and intent of Congress?

Answer: The transfer of the family planning program to the Office of Population Affairs in the OASH has consolidated related Public Health Service programs in Adolescent Family Life, Population Affairs, and Family Planning. The transfer has also improved management efficiency and coordination by providing consistency and by minimizing administrative costs.

Furthermore, the current delegation of authority has brought the family planning program organizational placement into conformity with the Title X statutory provisions regarding the responsibility of the Deputy Assistant Secretary for Population Affairs (DASPA) for administering family planning programs. The Title X legislation directs that the DASPA shall "administer all federal laws for which the Secretary has administrative responsibility and which provide for or authorize the making of grants and contracts related to population research and family planning programs."

A number of accomplishments since the transfer of the program illustrate the way in which program management has been enhanced and the goals of the program have been furthered. For example, a

National Institutes of Health managed peer review process for service delivery improvement research proposals was established for the first time in 1983. We are confident that this scientific review process will result in selection of the best research projects. Another accomplishment since the transfer has been the plan to bring in-house a data analysis function which in recent years was done by grant or contract. The office will analyze existing data from the National Center for Health Statistics, the Census Bureau, grantee automated data system, and other sources of pertinent data in order to provide information on women-in-need of family planning services and the number and characteristics of family planning patients served by organized programs and private physicians. The Department has increased its capability to do preliminary and varied data analyses. This change is a positive step in a series of modifications and improvements to the data collection process over the last seven years.

Question: Secretary Heckler's letter said the Department's decision "eliminated the split between the setting of overall policy and the operations which implement the policy." It sounds like she was talking about two different departments rather than two agencies under her own roof. Why can't she still control the policy and operations of an agency -- Health Resources and Services -- which she administers?

Answer: The split referred to by Secretary Heckler involved having policy established at one level within the department and the implementation at another level when the Title X statute established the position of the Deputy Assistant Secretary for Population Affairs to be responsible for Family Planning programs. Putting policy formulation and implementation within one office under the supervision of the DASPA simplifies program administration.

Question: Why couldn't you have distributed the money normally and asked each area to do some work on the so-called national priorities? In this way, no region would have had to take what amounts to a cut in the face of an overall program increase.

Answer: The allocation of family planning funds is based on objective data and an analytically objective formula that consider the differences between regions regarding need and performance and also provides an adequate measure of funding stability. This year the bulk of the initial regional allocations was based on a three-part formula:

1. Twenty percent (20%) was prorated to the regions based on the number of poor women-in-need of family planning services in each region.

2. Thirty percent (30%) was prorated to the regions based on performance, the number of women below 150 percent of the poverty level actually served at the regions' grantee clinics compared to the national total.

3. Fifty percent (50%) was a funding stability allotment based on the amount each region received in prior years.

The funds that have been identified for national priority or special projects will be spent for family planning services. The areas that have been identified for national priorities, such as natural family planning, infertility, and family involvement, are part of the services that Title X providers are required to provide by law. These funds will be used to support local programs.

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## Questions Submitted by Senator William Proxmire

### PAYMENTS TO HAWAII

Question: Your budget justification for the Hawaiian Hansen's Disease program projects an increase of almost 12 percent for inpatient per diem costs between 1983 and 1984 but only a 4.6 percent increase between 1984 and 1985. Can you tell us why you believe the rate of increase will be cut in half?

Answer: The rate of increase will be reduced due to a lower overall rate of inflation and through improved management of the program.

Question: What's your rationale for cutting Federal costs sharing under Hawaii's Hansen's Disease program from 61 percent in 1984 to 50 percent in 1985?

Answer: In FY 1984, the U.S. Congress provided an additional $294,000 over the Administrator's FY 1984 budget request, thereby increasing the Federal government share to that program. Historically, the Federal government share has been between 50 and 53% over the last five years with the exception of FY 1984. The budget request resumes the historical pattern.

### NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Question: Dr. Graham, once again this year you are proposing the termination of the National Health Service Corps Scholarship program. Under your proposal no new scholarships would be provided.

Last year, in a response for the record, you told the Committee that you were considering various options to provide personnel for health manpower shortage areas in lieu of scholarships. You mentioned specifically a limited renewal of the scholarship program, program of loan forgiveness in exchange for the agreement to serve in an underserved area for a fixed period, and the use of volunteers who, as Federal employees, would work in underserved areas.

Your answer also stated, "Preliminary recommendations of the study group have been completed are currently being reviewed with the Department." This was the situation about 12 months ago. Where do these recommendations stand today?

Answer: The recommendations are still under consideration in the Department.

## NATIONAL HEALTH SERVICE CORPS DEBT COLLECTION

Question: Last year you informed the Committee that your target for collecting National Health Service Corps debt was $14,690,000 for fiscal year 1983 and $14,059,000 for the current fiscal year. How much money did you ultimately collect in fiscal year 1983?

Answer: We collected $18,118,000 in FY 1983.

Question: Do you still hope to meet your 1984 target of $14,059,000?

Answer: We expect to meet or exceed the $14,059,000 level of collection in FY 1984.

Question: What is your NHSC debt collection target for fiscal year 1985?

Answer: Our target for FY 1985 is approximately $15,000,000.

## HEALTH PROFESSIONS DEBT COLLECTION

Question: Last year, Dr. Graham, in a record response, you submitted a health professions loan delinquency table that showed almost 16 percent of borrowers were delinquent for over 90 days on about 11 percent of loan dollars outstanding. That was the picture as of June 30, 1982. Can you tell us what those percentages are as of the most recent date for which you have statistics?

Answer: As of June 30, 1983, there was a 7 percent dollar delinquency rate on Health Professions Student Loans delinquent 60 days or more.

Question: Last year you indicated that your target is to reduce the loan delinquency rate to no more that 5 percent over the next 2 years. Are you confident that you will meet that goal within the next 12 months?

Answer: Most schools have made significant improvements in reducing their delinquency rates over the past two years. We believe that most health professions schools will be able to meet the delinquency target of 5 percent, however, many nursing schools may have difficulty in meeting that target. We are currently reviewing both the performance standards requirements and the delinquency formula calculations and will be establishing new targets soon.

## HEALTH PROFESSIONS STUDENT LOANS

Question: Last year you estimated $42.8 million in revolving funds would be available to make health professions loans to 21,400 students in fiscal year 1984. You have revised that estimate upward to $49 million, which will allow schools to make loans to 24,500 students -- an increase of about 20 percent. Why was your initial estimate so wide of the mark?

Answer: The initial estimates were made based on data available at the time, which was academic year 1981-82 data. Since the initial estimates were made, more recent data (from the academic year 1982-83 annual operating reports prepared by the schools) have been used and these reports reflect increases in collections as a result of the Department's stricter requirements for the schools in the collection of delinquent loans.

## HEALTH PROFESSIONS PHYSICIAN GLUT

Question: Dr. Graham, last December the new President of the Mount Sinai Medical Center, Dr. Glenn, predicted that medical schools and hospital training programs will double the number of physicians in this country within the next 20 years, producing a glut that will drive up health costs and encourage unnecessary medical care.

Dr. Glenn cited estimates that each physician accounts for the expenditure of over $300,000 a year in public funds. He urged New York state's medical schools and health and education officials to develop a policy for controlling the number of medical schools, students and medical specialists.

Your bureau will be assisting 24,500 health professions students in fiscal year 1985 through the health professions student loan program. I assume that a great many, if not a majority, of these students are in medical schools. Are you concerned about the oversupply problem, and if so, is the bureau taking any steps to deal with it?

Answer: Fifty-four percent of students who borrow through the Health Professions Student Loan Programs are medical students. Medical and osteopathic students must demonstrate "exceptional" financial need. Therefore, we believe we are assisting students who otherwise may not be able to pursue a health career. Such limited assistance remains an Administration priority and will have little effect on a projected oversupply of physicians.

## HEALTH EDUCATION ASSISTANCE LOANS

Question: Last year you estimated that non-Federal lenders would provide $175 million in new Federally guaranteed loan funds under the Health Education Assistance Loan (HEAL) program in fiscal year 1984. Your current estimate for 1984 is $250 million in guaranteed loans, an increase of 43 percent over your original estimate. Why was your initial estimate so low?

Answer: In FY 1984, the Administration's budget requested $175 million for new loan guarantee authority. Congress, through the appropriations process, allowed commitments for new loan guarantees to be made up to the full legislatively authorized level of $250 million.

Question: You also indicated last year that the average amount of a loan in 1984 would be $10,000. Now you estimate that the average student will borrow $12,000 in 1984. The average loan was $9,000 last year. Can you tell us why the average loan has gone up be one-third in just one year?

Answer: The average amount for each loan is still estimated to be approximately $10,000 in FY 1984, however, we anticipate a student will borrow approximately $12,000 in FY 1984 using one or more loan sources.

## HEALTH EDUCATION ASSISTANCE LOANS

Question: In view of the fact that you sharply underestimated your 1984 new guaranteed loan volume last year, projecting a reduction of $50 million whereas it now looks as though there will be an increase of $25 million, isn't it reasonable to think your 1985 estimate, which projects a reduction of $75 million below the current level, may be too low?

Answer: The President's FY 1985 budget request anticipates a carryover of $135 million into FY 1985 for a a total availability of $310 million. We, therefore, believe that the $175 million in new loan guarantee authority requested in FY 1985 will be sufficient to meet the demand.

## HEALTH TEACHING FACILITIES

Question: Last year at this time you estimated $3.7 million would be needed to pay interest subsidies on guaranteed health professions teaching facilities loans. Your current estimate for fiscal year 1984 is $20,814,000, an increase of $17.1 million above your initial estimate. Can you tell us why your initial estimate was so wide of the mark?

Answer: Our original estimate of $3.7 million required for FY 1984 was reduced to $0.8 million, as a result of the full repayment of the Meharry loan and the estimated availability of $0.4 million in carryover funds from FY 1983. The $0.8 million in new budget authority, along with the $0.4 million in carryover funds, provided $1.2 million to make the interest subsidy payments in FY 1984.

The current estimate for FY 1984 of $20.814 million represents obligations, which also includes $19.5 million appropriated to us in FY 1983 for construction assistance grants to the Oregon Health Sciences Center in the amount of $14.5 million and to the Morehouse College of Medicine in the amount of $5 million.

Question: This year you plan to use $13,569,000 in unobligated health teaching facility funds for pay costs. Why are these funds no longer needed for construction projects and interest subsidy payments?

Answer: The funds we plan to use for pay and other costs consist of $6.2 million, which was not required in FY 1983 to fully repay the Meharry defaulted loan, and $7.5 million recaptured from previous recipients of Federal health construction grants. Recaptures generally result when a final audit close-out of the grant following completion of construction indicates that some of the total amount initially provided to the grantee was either unneeded or did not meet matching requirements.

We are no longer making construction grants and these funds were not appropriated initially for the payment of interest subsidies.

## FAMILY MEDICINE VS. INTERNAL MEDICINE AND PEDIATRICS

Question: Dr. Graham, in February you submitted a report to this Subcommittee on the differential in the cost per medical resident between the Family Medicine program and the General Internal Medicine and Pediatrics program. Your 1984 budget justifications projected a cost per family medicine resident of $3,904 compared with a general internal medicine and pediatrics cost of $12,387 per resident. Your February report indicated that actual costs in 1983 were $6,259 per family medicine resident and $9, 641 per internal medicine - pediatrics resident. Why were your initial estimates so wide of the mark?

Answer: Our FY 1984 estimates mainly reflect mathematical variances which result from the division of the number of residents into Federal grant dollars awarded. Unfortunately, this does not accurately reflect the total program cost per resident. Factors which appear to contribute to the differences in the Federal share of the training cost per resident in Family Medicine versus General Internal Medicine and General Pediatrics appear to be as follows: Family Medicine training programs are based in community hospitals and receive State and local government support whereas General Internal Medicine and General Pediatrics training programs are typically based in clinical settings of tertiary care teaching hospitals and do not receive significant support from State funding sources.

Question: Because of the change in cost estimates you obviously will be able to train more general medicine - pediatrics residents and fewer internal medicine residents per million dollars of expenditures in FY 1984 than you originally projected. How can you hope to prepare budgets in these areas that are responsive to need if your estimating procedures are so faulty?

Answer: It is difficult to prepare highly accurate budget projections with the limited data bases available at the time budget estimates are prepared. However, the Administration is responsive to this need by updating the information base each year with the most current data from the latest application cycle.

Question: Your February report states that "the Public Health Service no longer requires all applicants to provide detailed information on the total costs of their training programs" and that, as a consequence "grant applications for the above-referenced programs do not contain sufficient data to fully respond" to our inquiry regarding the reasons for the cost differential between the two programs. If the applications you receive don't provide detailed total cost information how can you make an objective decision regarding the most cost-effective way to allocate residency training dollars among grant applicants?

Answer: These are "last dollar" programs, that is, the Federal Government support is for that portion of total program costs that cannot be met by other sources of funding. The burden of proof is on each applicant to define its program objectives and defend its funding needs. Using the data available, objective decisions are made to the extent possible. Although the data base is less than perfect, some balance should be maintained between what data are needed for decision making and excessive reporting burdens for applicants.

## HEALTH PROFESSIONS ANALYTICAL STUDIES AND REPORTS

Question: Last year, in a response for the record, you stated that the Health Professions Analytical Studies and Reports program had been funded at the same level in fiscal years 1982, 1983, and 1984, with a minor increase in 1984. What reports or studies were prepared with these funds in fiscal years 1982 and 1983? Provide a title and a one paragraph description of each report and study together with the cost of each for the record.

Answer: Studies funded under the Health Professions Analytical Studies and Reports program for fiscal years 1982 and 1983 are indicated below, along with costs and brief descriptions of the projects.

### HEALTH PROFESSIONS ANALYTICAL STUDIES FUNDED IN FY 1982

| Title | Amount Awarded | Purpose |
|---|---|---|
| Maintenance and Update of BHPr Computerized Analytical Data Base | $174,515 | To implement, and integrate into the Area Resource File (ARF) data system an automated data dictionary/directory system capability to extend the flexibility and accessibility of the data base. |
| Implementation of Revised Criteria for Designation of Primary Care and Dental Shortage Areas | $105,997 | To implement the new criteria (revised under Sect. 2702(c) of the Omnibus Budget Reconciliation Act of 1981) for primary care medical and dental shortage area designations, and to enhance designation data update and reporting capabilities. |
| Development of Revised Criteria for Designation of Shortage Areas for Vision Care, Podiatric Care, Pharmacy, and Veterinary Care | $109,852 | To evaluate existing shortage area criteria for vision, podiatric, pharmacy, and veterinary care, and identify possible refinements and/or revisions to those criteria. |
| National Sample Survey of Licensed Practical/ Vocational Nurses (Phase I) | $201,909 | To develop and test a survey instrument to obtain analytical data on personal and employment characteristics, and on the current supply of licensed practical nurses. |

| Title | Amount Awarded | Purpose |
|---|---|---|
| In-Depth Examination of 1980 Census Data on Health Occupations | $157,309 | To examine, evaluate, and compare 1980 Decennial Census employment data in health occupations to other specific workforce surveys; to serve as a data source for analysis of health occupation supply and requirements for both US and State levels. |
| Supply, Distribution, and Activities of Psychologists (Phase I) | $195,215 | To obtain a national data base of basic descriptive information on all psychologists holding doctoral degrees, and those with masters degrees providing mental health services in order to provide part of the data base needed to develop mental health shortage areas, and to develop a survey instrument for a sample study of clinical psychologists. |
| Further Development of Computer Models for Nurse Projections | $51,489 | To provide information on nursing supply, requirements and distribution and to develop refined projections of the supply of and requirements for nurses; to tabulate and assess data on institutions and individuals for computer models used to project future nurse supply and requirements. |
| Refinement of the Health Professions Requirements Model | $74,413 | To revise and expand the BHPr Health Professions Requirements Model and to generate projections to the year 2000 under alternative assumptions. |
| Analysis of the Distribution and Output of Vision Care Providers | $ 98,000 | To provide updated information on vision care providers through a comprehensive study of the geographic distribution and output of optometrists and ophthalmologists; and to support refined projections of requirements for vision care providers. |

| Title | Amount Awarded | Purpose |
|---|---|---|
| A Study of Dental Graduates Employment Patterns (Phase I) | $ 66,232 | To review pertinent literature, prepare survey design, and develop data collection instruments to identify distribution and other characteristics of recent dental graduates. Survey to be conducted in Phase II of contract. |
| Characteristics of Dental Hygiene Practice in Non-Traditional Settings, (Phase II) | $118,646 | To collect and analyze data and prepare a report on the nature and characteristics of dental hygiene practice in settings other than dentists' offices; functions performed, supervision requirements, patients and population served, and other characteristics of such dental hygiene practices. |
| Time Series Forecast Model on Potential Impact of Increased Numbers of Physicians (Phase I) | $119,369 | To develop a strategy and plan, using time series forecast model, to investigate the potential effect of the increasing number of physicians on the access to and the nature, scope, and cost of medical care delivery. |
| Analytical Studies in Graduate Medical Education | $440,000 | A series of studies on the supply and characteristics of physicians in graduate medical education. |
| Basic Data Development | $154,812 | To obtain basic data related to the various health professions for use in analytical activities. |
| Computer Support Services | $210,134 | To provide computer system support essential to the conduct of these analytical studies. |

HEALTH PROFESSIONS ANALYTICAL STUDIES FUNDED IN FY 1983

| Title | Amount Awarded | Purpose |
|---|---|---|
| Workshops on Implications of Health Promotion and Disease Prevention | $141,417 | To manage and conduct five workshops to explore the 15 priority areas for improving the Nation's health identified in Objectives for the Nation--Promoting Health and Preventing Disease based on the Surgeon General's Report on Health Promotion and Disease Control. |
| Workshop on Shortage Area Designation | $47,945 | To manage and conduct a workshop on current health manpower shortage area designation policies and procedures, primarily for State health and health planning agency representatives in Regions VI through X, similar to the Workshop held in November 1982 for representatives from Regions I through V. Representatives of health professions associations invited to participate. |
| Updating and Refinement of the Health Professions Requirements Model | $271,518 | To revise and expand the BHPr Requirements Model by: 1) examining pertinent literature on consumer demand for health services, including appraisal of technological advances likely by year 2000; 2) preparing a report on alternative strategies for projecting consumer demand for health services; 3) creating a computer data base describing current and future consumer health status; 4) developing adjustment factors for health service utilization by year 2000; and 5) modifying present computer programs to incorporate results of contract tasks. |

| Title | Amount Awarded | Purpose |
|---|---|---|
| Study of Nursing and Related Personnel in Nursing Homes (Phase I) | $300,000 | Inter-agency agreement with NCHS to expand its sample nursing home survey to include the collection of needed data on facilities and personnel staffing in nursing homes; in particular, to obtain data on factors related to the recruitment and retention of RNs. |
| Analysis of 1981 Survey of Physician Assistants Data | $9,577 | To provide partial funding to NCHSR for compilation and analysis of computerized data from the Duke University Medical Center's 1981 Survey of Physician Assistants. |
| Extension of the National Time Series Forecasting Models | $295,151 | To disaggregate econometric forecasting models to allow models to forecast at a more detailed level. Current models forecast broad medical components of the CPI, national health care expenditures, aggregate supply of physicians, dentists, nurses, and hospital beds. This contract augments the model's data base, and scope of specifications will be extended to include medical service types, medical specialties, and geographic regions, to improve long-term forecasting and policy impact analysis. |
| National Sample Survey of Licensed Practical/ Vocational Nurses (Phase II) | $407,288 | To obtain data on the number and characteristics of licensed practial nurses in the U.S. Involves collection and analysis of data to include employment characteristics, status, geographical distribution, mobility (geographic and educational), educational plans, and licensure. Implications related to nursing resources and the utilization of licensed practical/vocational nurses in |

| Title | Amount Awarded | Purpose |
|---|---|---|
| | | the health care system will be assessed. |
| Development of a Graduate Medical Education (GME) Program Data File (Phase I) | $99,938 | To collect program level data on Graduate Medical Education (GME) from both published and unpublished sources, focusing on medical specialties from 1975 to present, and to develop a systems file in which these data will be placed, in order to assess trends in GME residency expansion and contraction position slots, applicants, and fill-in rates. County/Health Services Area (HSA) Access System of the Area Resource File (ARF) software will be supplied to Contractor, in order to link elements of GME file with selected elements from the ARF and/or State National Timeseries System of ODAM/BHPr. |
| Determination of Supply and Requirements for Public/Community Health Personnel (Phase I) | $205,165 | To develop, test, and refine data collection instruments to be used in gathering information on availability, deployment, and utilization of the public health workforce. Traditional classifications such as epidemiologist, biostatistician, health administrators etc. as well as functional classifications will be addressed. A sampling plan for employees and employers (e.g., State and local health departments, planning agencies; welfare and rehabilitation agencies) will be developed and tested for validity, reliability, and accessibility. |

| Title | Amount Awarded | Purpose |
|---|---|---|
| Expansion of the Area Resource File (ARF) System for Health Professions Support | $343,662 | To maintain, update, and develop the ARF system to make it more useful, more efficient, more effective, and more easily available to health manpower analysts. The ARF system data base, organized in 4 major files--County, Hospital, Nursing Home, and State/National Timeseries--and more than 75 minor computer files which may be limited or used separately, is used for (1) analysis of health manpower supply and requirements, (2) shortage area designations, (3) planning, and (4) related technical analyses such as health care system interaction and health status causation. The ARF ACCESS Systems and Data Dictionary/Directory System (DD/DS) will be implemented, maintained and expanded. |
| Linkage of Physician Supply and GME Model to Refine Econometric Model Relating Policy Variables to First-Year Residency Distributions (Phase I) | $198,367 | To extend the research and modeling activities developed by the Office of Graduate Medical Education (OGME) and other agencies to assess the impact of policy variables on the size and specialty distribution of first-year residents and on future number and specialty distributions of practicing physicians. Assessment to be made by construction of an econometric model and incorporating results in the GME projections model. |
| Development of Revised Criteria for Designation of Mental Health Manpower Shortage Areas | $131,487 | To develop measures for evaluating the relative contributions of psychiatrists, clinical psychologists, psychiatric nurses, and psychiatric social workers to the provision of various aspects of |

| Title | Amount Awarded | Purpose |
|---|---|---|
| | | mental health care to the U.S. population, for use in development of criteria for mental health manpower. To analyze existing data on productivity, utilization of various types of mental health care providers by settings and types of mental disorders; to analyze the relative occurrences of various types of mental disorders by age, sex, income, ethnic, geographic and other pertinent categories of persons affected; and to evaluate various measures of utilization of different types of mental health care professionals. |
| The Third National Sample Survey of Registered Nurses (Phase I) | $130,030 | To obtain current data on the numbers and characteristics of registered nurses in the U.S., relevant to ensuring sufficient and qualified RN's to meet the needs of the U.S. population. Two prior sample surveys providing data files on supply need to be examined, up-dated, and monitored to properly assess the role of RN's in the health care system and the state of RN resources. A survey of a sample of all RNs with current licenses will be used to obtain data on activity status, educational background, employment distribution, geographic location, mobility, and trends in supply and distribution of RN's. Phase I involves preparation and testing of data collection instruments. |

| Title | Amount Awarded | Purpose |
|---|---|---|
| Analysis of the Current Level of Resources Used in Geriatric Dental Education (Phase II) | $49,887 | To collect, analyze, evaluate, and report on data describing the current level of resources used to train dental students in geriatric dentistry. In particular, to survey and evaluate the content and characteristics of the curricula in geriatric dentistry in the Nation's 60 accredited dental schools. |
| Employment Trends in Hospitals | $143,786 | To obtain a statistical analysis of the factors affecting hospital staffing patterns and employment levels of nursing and allied health occupations, using data collected over a 3-year period (since 1980) by the American Hospital Association (AHA), and others. An integrated data file covering 1980-82 is to be constructed from the AHA Annual Survey data, and the Area Resource File is to be used as a source for market area characteristics. At least nine broad health occupations are to be analyzed in terms of supply, requirements, employment and vacancy trends and levels as related to specific hospital and market area characteristics. |
| Comparative Evaluation of National Health Service Corps Alumni Retained in Health Manpower Shortage Areas | $37,794 | To investigate and compare types of rural service communities, particularly those in which the National Health Service Corps (NHSC) alumni and Private Practice Option (PPO) physicians have established practices; to analyze community factors in location choices by new primary care physicians; to compare those communities selected by NHSC assignees, alumni, and PPO physicians with those of primary |

| | | |
|---|---|---|
| | | care MD's not in the NHSC program; and to assess whether placement of NHSC physicians alters distribution patterns otherwise expected. |
| Follow-up Survey of Optometry Graduates to Determine Practice Patterns | $35,000 | To update data and verify trends relative to the practice patterns of recent optometry graduates. |
| Basic Data Development | $21,846 | To obtain basic data related to the various health professions for use in analytical activities. |
| Computer Support Services | $251,971 | To provide computer system support essential to the conduct of these analytical studies. |

## HEALTH PROFESSIONS ANALYTICAL STUDIES AND REPORTS

Question: What reports and studies do you plan in fiscal year 1984 and 1985? Provide a one paragraph description and cost estimate for each report and study for the record.

Answer: Analytical studies under consideration for funding in fiscal year 1984 are indicated below. A brief description of each project is included, but the estimated costs of the individual projects are not indicated, since the competitive bidding process might be compromised by doing so.

Planning for fiscal year 1985 projects has not yet been completed, but a list of potential project topics for 1985 funding is presented below.

### HEALTH PROFESSIONS ANALYTICAL STUDIES FUNDED IN FY 1984

| Title | Purpose |
|---|---|
| Refinement, Development and Analysis of Nursing Data Bases for Computer Projection Models | To provide the development and analysis necessary to update the major data bases used in the projection models for nursing education and nurse supply and requirements. These data bases are periodically reviewed for completeness and content, and modified and updated to reflect the latest available data. Several of these data bases will be addressed in this project: Licensed Practical/Vocational Nurse (LP/VN) educational data will be incorporated into the Basic Nursing Education Comprehensive Data File, and the results of the LP/VN National Sample Survey will be used to structure several data bases for the supply and projection models. Additionally, two years of data on Registered Nurse education, and two years of data on hospitals will be added to pertinent data bases. |
| Validation of the National Medical Association Masterfile of Black Physicians | To validate and update data on black physicians contained in the National Medical Association Masterfile of Black Physicians, |

| Title | Purpose |
|---|---|
| | to provide a validated base of information and data for use in analysis of black physician supply and characteristics. |
| Analysis of Trends in the Supply, Distribution and Educational Background of Physicians in Selected Urban Areas | To access an existing proprietary data base to analyze changes at the census tract level in the supply and distribution of physicians in ten cities over a seventeen year period (1963-1980). The study will give special attention to analyses of changes which occurred in low-income areas and identify:<br>(a) overall and city-specific trends in the supply and distribution of physicians, by age, specialty and major professional activity;<br>(b) differences over time in the educational background and experience of physicians practicing in low income and other areas; and (c) changes in the supply distribution and other characteristics of physicians as compared to changes in use of hospital emergency room and outpatient department, (EF/OPD) services in census areas. |
| A Study of Dental Graduates Employment Patterns (Phase II) | To implement an approved protocol for collecting and analyzing survey data obtained from recent dental graduates concerning distribution and determinants of dental graduate employment. |
| Analysis and Exchange of Information and Data on State Credentialing of Health Personnel | To provide timely information on State credentialing of health personnel. The project will involve compilation of statutes, administrative codes, rules and regulations promulgated by the States. For key items of information, a computerized coding, storage and retrieval |

| Title | Purpose |
|---|---|
| | system will be established, and the actual text of State codes and regulations will be maintained in files for special manual searches and analyses. |
| Analysis and Improvement of the Projection Models for the Supply and Requirements for Licensed Nurses | To upgrade specific areas of the nurse projection models to provide improved and updated analytical capability to assess the current and future status of nurse supply and requirements in the health care system, both nationally and within each State. The results of this project will provide a necessary tool to asess the current and future effects of the training of nurses, utilization and expenditures in the health care system, and the modes of delivery and provision of services on nurse supply and requirements. |
| Time Series Forecast Model on Potential Impact of Increased Numbers of Physicians (Phase II) | To extend the basic Time Series Forecast Model utilized in Phase I of this project to incorporate particular consideration of the impact of an increased number of physicians upon (1) changes in physicians' specialties and sub-specialties; (2) changes in physicians' geographic locations; (3) the roles and capacities of medical and osteopathic schools and teaching hospitals; and (4) patterns of third party payments. |
| Expansion of the Area Resource File System (ARF) for Health Professions Support | To support the quarterly update, revision, and expansion of this major Federal statistical system of data bases, as well as the continued enhancement of its software systems; to adjust documentation for these changes; to expand analytic datafiles; to identify and acquire important new data; and to improve user-support software systems. |

| Title | Purpose |
|---|---|
| Preventive Health Care in Medical Residency Training | To examine residency training in several medical specialties to determine the extent and depth to which residents are prepared to provide preventive health care in clinical practice. |
| Assessment of Osteopathic Medical Education and Practitioner Data | To assess the current status of data collected on osteopathic physicians and medical education in terms of national information needs, and, utilizing information obtained on graduate osteopathic medical education, to develop a plan to determine the extent to which osteopathic interns and residents in the primary care specialties of general practice, general internal medicine, obstetrics and gynecology, and general pediatrics are prepared to provide preventive health care in clinical practice. |
| The Third National Sample Survey of Registered Nurses (Phase II) | To obtain data on the numbers and characteristics of registered nurses in the country. The data to be obtained are relevant to the investigation of issues related to nursing, particularly those involved in ensuring that there are sufficient and adequately qualified registered nurses to care for the needs of the population. Phase II involves data collection, tabulation, and preliminary analysis. |
| Linkage of Physician Supply and GME Model to Refine Econometric Model Relating Policy Variables to First-year Residency Distributions (Phase II) | To develop a model to ascertain the relationship between size of graduate medical education programs and factors which impact on residencies such as service load, area demand, teaching requirements of residents, funding of residents and the presence of foreign medical |

| Title | Purpose |
|---|---|
| | graduates (FMGs). This model, which specifically focuses upon policy variables as they impact upon the distribution of total first year residents across medical specialties, will then be linked to Graduate Medical Education (GME) and physician supply models. |
| Development of a Graduate Medical Education (GME) Program Data File (Phase II) | To expand the development of a residency program data file through additional data sources. The purpose of constructing the file are to assess trends in the distribution of residents across programs, changes in the types of residencies offered, and changes in the characteristics of particular types of residency programs. |
| Study of Nursing and Related Personnel in Nursing Homes (Phase II) | Inter-agency agreement with NCHS to conduct data collection and compilation activities on facilities and personnel staffing in nursing homes. |
| A Tandem Study of Black Physicians in the FY 1985 National Ambulatory Care Survey (NAMCS) | To determine the practice patterns, and patient profiles of Black physicians. This information is important in evaluating one of the basic assumptions of the Health Careers Opportunity Program, i.e., that Black Physicians are more likely to practice in minority communities than non-minority physicians. The proposed survey will help determine not only whether Black physicians are fulfilling that expectation, but whether they engage in the types of practice which focus on the particular needs of lower-income persons. |

| Title | Purpose |
|---|---|
| Update of Basic Data on Physician Characteristics | To acquire current data and tabulations on physician characteristics on a continuing basis to be used in a variety of programs and analytical activities. |
| Basic Data Development | To obtain basic data related to the various health professions for use in analytical activities. |
| Computer Support Services | To provide computer system support essential to the conduct of these analytical studies. |

## HEALTH PROFESSIONS ANALYTICAL STUDY TOPICS FOR FY 1985

- Development of Options for Defining Mental Health Provider Shortage Designation Criteria
- Maintenance of Area Resource File System Data Base
- Computer support for basic analysis
- Purchase of Data Tapes
- Analysis of Nursing Home Staffing Patterns and Interactions Among Professions
- Analysis of RN Characteristics and Distribution
- Development of Data and Analysis for the Report to the President and Congress on the Status of Health Professions Personnel in the United States
- Update of Estimates of Supply of Health Professions Personnel

## HEALTH PROFESSIONS DIRECT OPERATIONS

Question: Last year you estimated your health professions peer review and National Advisory cost at $405,000 in fiscal year 1983 and stated that the cost would be somewhat less in 1984. How much did you actually spend on this activity last year and how much do you plan to spend in fiscal years 1984 and 1985? Give us an estimate in dollars.

Answer: In fiscal year 1983 our actual cost for the health professions and nursing peer review and the National Advisory Council meetings was $347,756. For fiscal year 1984 our estimates for these costs were revised to take into account the increase in programs allowed in the appropriation. The revised 1984 estimate is $465,000. In fiscal year 1985 we expect to expend approximately $300,000 for these purposes.

## COMMUNICATIONS, UTILITIES, RENT

Question: Last year's budget appendix estimated that HRSA would obligate $2,527,000 for communications, utilities, and rent other than standard level user charges in fiscal year 1983. According to this year's appendix you actually obligated $4,047,000 for this purpose, an increase of 60 percent over your estimate. What factors caused this substantial increase in your original estimate?

Answer: At the time that the 1984 budget request was prepared, the Health Resources and Services Administration (HRSA) was in the process of relocating the staff of a predecessor unit, the Health Resources Administration (HSA), from the Center Building in Hyattsville, Maryland to the PHS Headquarters at the Parklawn Building in Rockville, Maryland. We did not know at that time what effect these relocations would have on the communications, utilities, and rent costs of the agency.

We do know that HRSA incurred substantial rent and utilities costs as a result of occupying the Center Building for a longer period than originally projected in 1983, and incurred substantial communications costs as a result of the communications required between staff in the Center Building and staff in the Parklawn Building prior to the relocation of all former HRA components to the Parklawn Building in order to administer the programs, and as a result of telephone changes associated with the relocation of staff.

During FY 1984, we should gain the experience necessary to project communications, rent and utilities costs more accurately since all relocations occurred in FY 1983.

## PERMANENT POSITIONS

Question: This year's budget appendix indicates there were 2,970 permanent positions within the Health Resources and Services Administration in fiscal year 1983. Last year's appendix estimated a total of 4,679 permanent positions in 1983. Your justifications indicate that total obligations paid for 4,603 positions last year. Can you tell us where you get the figure shown in this year's appendix?

Answer: In the FY 1984 budget appendix, OMB had permitted HRSA to consolidate the direct and reimbursable positions, thereby reporting only one number for full-time permanent positions. However, in the FY 1985 budget appendix, OMB required a breakout of direct and reimbursable positions.

The FY 1985 budget appendix states that 2,970 are the FY 1983 actual permanent positions in direct funding and 460 are reimbursable full-time permanent positions. As such, the total FY 1983 actual full-time permanent positions is 3,430.

The FY 1983 total of 4,679, which was shown in the FY 1984 budget appendix, was the estimated total for direct and reimbursable full-time permanent positions. This total reflects the authorized position level of 2,115 provided for in the FY 1983 continuing resolution for the NHSC. However, the actual positions reported for the NHSC were lower than the authorized positions for two reasons: (1) the Departmental reporting system does not include civilian employees in the full-time permanent positions. As such, they are counted as temporary employees because their period of employment in the NHSC is three years or less; and (2) placement of health providers in the private practice option had greater success than anticipated in FY 1983.

The FY 1982 total full-time permanent positions of 4,603 included 2,115 authorized positions for the federally salaried field strength in the NHSC rather than the actual number of 1,891 which was required in 1982.

## PAYMENT TO HAWAII - HANSEN'S DISEASE

Question: Last year your justifications for payments made to the state of Hawaii for the care and treatment of persons with Hansen's Disease included a table which showed outpatient visits and cost per outpatient visit. This year's table does not provide that information. For the record submit the table printed on page 119 of your justifications augmented with information on outpatient visits and costs per outpatient visit for fiscal years 1983, 1984, and 1985.

Answer: The Hansen's Disease inpatient and outpatient data for the State of Hawaii is as follows:

| | 1983 Actual | 1984 Estimate | 1985 Estimate |
|---|---|---|---|
| Average Daily Patient Load | 102 | 102 | 102 |
| Patient Days | 37,230 | 37,332 | 37,230 |
| Inpatient Per Diem Cost | $83.86 | $93.73 | $98.32 |
| Outpatient Visits | 1,600 | 2,000 | 2,000 |
| Per Visit Cost | $76.61 | $66.68 | $70.17 |
| Total Program Cost | $3,241,316 | $3,623,256 | $3,800,795 |
| Appropriation Requested | $1,732,000 | $2,200,000 | $1,905,000 |
| Percent of estimated cost supported by request | 53% | 61% | 50% |

## EQUIPMENT

Question: Last year's budget appendix estimated HRSA equipment expenditures of $371,000 in fiscal year 1983. Your actual equipment expenditures according to this year's appendix were $2,123,000. Please explain the discrepancy.

Answer: At the time the FY 1984 budget appendix was prepared, the FY 1983 column of the FY 1984 budget reported an estimate of $371,000 which was comprised of amounts from two separate agencies, the Health Resources Administration and the Health Services Administration. This amount grossly underestimated the need required for the reorganization of these agencies into the Health Resources and Services Administration and the relocation of significant portions of the new Agency.

The actual FY 1983 obligation of $2,123,000, which is shown in the FY 1985 budget appendix, reflects the purchase of automatic data processing equipment, such as prototype machinery and word processing equipment. This equipment is being used to provide accurate, timely, and usable data to aid in fulfilling the mission of the Health Resources and Services Administration.

## NURSING RESEARCH

Question: Provide for the record a listing of the resources devoted to nursing research throughout the Department. I understand that there have been resources dedicated to nursing research in addition to the line item Congress provides and it would be helpful to know the total extent of the Department's efforts.

Answer: The principal Federal support of nursing research is funded by the Division of Nursing in the Health Resources and Services Administration's Bureau of Health Professions. Precise information is not available on nursing research supported by other DHHS components, such as the National Institutes of Health and the National Center for Health Services Research.

Question: What is the projected cost of establishing a National Institute on Nursing Research at NIH?

Answer: We estimate that the cost of establishing a National Institute for Nursing Research as proposed by the "Tri Council on Nursing" would range between $8 to $9 million and would require from 100 to 120 positions.

Question: What steps has the Department taken to increase the visibility and priority given to nursing research to date and what are your future plans?

Answer: Two new nursing initiatives were authorized early in FY 1984: The New Investigator Nursing Research Awards and the Utilization of Research in Nursing Awards. The positive response from the nursing profession is reflected in a substantial increase in research proposals submitted as of March 1.

The Department is reviewing ways to strengthen nursing research in the Public Health Service. Options being considered include:

further strengthening the research programs in the Division of Nursing in HRSA's Bureau of Health Professions; changing the Division of Nursing to a Bureau; and consideration of other alternatives.

## NATIONAL HEALTH SERVICE CORPS

Question: Could you describe for the record the ways in which the three type of placements (regular NHSC personnel, Private Practice Option and Private Placements) differ? What are the differences in financial commitments by the Federal government, the commitments of the individuals and the number of individuals now in place in each option?

Answer: NHSC providers may be assigned to Health Manpower Shortage Area (HMSA) communities in one of three ways as follows:

1. Federal Employment - scholarship recipients and volunteers are assigned as civil service or commissioned corps employees of the NHSC. This type of assignment is reserved for high-need communities where private placement is not feasible or there is an insufficient economic base for placement under the PPO.

2. Private Practice Assignment (PPA) - scholarship recipients are assigned to Community Health Centers and Migrant Health Centers as private practitioners. Funding for these individuals is provided to the centers through Federal grants to offset salary and benefit costs. Private practice assignees are members of the NHSC, are subject to the personnel system of the entity to which they are assigned, and receive at least the same income as they would have received as a Federal civil service employee of the NHSC.

   The legislative authority for the PPA may be found in Sections 331(a)(1)(c), 331(d)(3) and 33(d)(1) of the Public Health Service Act as amended.

3. Private Practice Option (PPO) - scholarship recipients enter into a written agreement with the Secretary under which the individual agrees to engage for a period equal to the remaining service obligation in the full-time private clinical practice (including service as a salaried employee in a entity directly providing health services) of his profession. PPO participants may not discriminate against individuals on the basis of their ability to pay for health services or because payment for health services will be made under Medicare or Medicaid.

   The legislative authority for the PPO may be found in Section 338C of the Public Health Service Act as amended.

   As of September 30, 1983, the NHSC field staff was composed of 1,452 Federal employees, 312 Private Practice Assignees. and 1,101 individuals serving under the PPO.

Question: How does the Department determine retention rates? Does this only apply to those who extend their Corps commitment?

Or does this include individuals who remain in an area on their own? If it includes the latter, does the Department maintain records on how long an individual remains in an area beyond the commitment required by the Corps?

Answer: In the past, the NHSC program has recorded the future plans of health providers (volunteer and scholarship) upon completing their obligated period in the NHSC. However, no follow-ups were made to verify the responses or to confirm long-term retention.

In FY 1984, the NHSC Scholarship program became responsible for the NHSC Alumni File and will update annually the data on NHSC providers (volunteers and NHSC scholarship recipients) regarding the type practices in which they are engaged and where they are practicing.

Question: What are your projections for the next four years of medical students who will become eligible for meeting their Corps commitment?

Answer: The projection for the next four years of medical students who will become eligible for service obligation is as follows:

| 1985 | 1986 | 1987 | 1988 |
|---|---|---|---|
| 1,481 | 1,191 | 1,144 | 239 |

Question: I understand that the Department uses a system to classify underserved areas and that you have focused upon sending Corps personnel to the most needy areas and this is commendable. However, some have questioned the actual differences between the most needy and least needy areas under your classification system and that, in reality, there is little difference between the classes. Please describe the system now in place for classifying areas based upon need and provide a detailed discussion of the differences between real communities that would fit in each grouping you employ.

Answer: The Department has a system of classifying underserved areas known as Health Manpower Shortage Areas (HMSA) which is based primarily on the health provider/population ratios and high need elements, such as an infant mortality rate exceeding 20 infant deaths per 1,000 live births, poverty levels exceeding 20 percent of the population and fertility rate exceeding 100 births/1000 women ages 15-44.

The Department receives demographic and health data for a specified HMSA and evaluates the data submitted for accuracy, the impact of contiguous areas on the delivery of health services within the HMSA and the availability of local and State health resources to provide health services. Upon completion of the evaluation of the data submitted, the Department assigns a degree of shortage to the underserved area, based on all of the above factors, on 01 degree of shortage is ranked first priority and 04 degree of shortage is ranked last or minimum priority. Each degree of shortage has a threshold number of health providers that cannot be exceeded or the area will lose its designation as an HMSA. This threshold is known as the dedesignation threshold and is monitored throughout the year. When private sector physicians enter into practice in a HMSA and they exceed the dedesignation threshold, the Department will not place the NHSC providers in that area and will withdraw the designation from this area.

Before the NHSC providers are assigned to a HMSA, State and local planning agencies have the responsibility for evaluating the relative needs of HMSA's within their States. Based on these evaluations, recommendations for assignment of personnel are submitted to the NHSC in priority order. The HMSA's, relative to their priority, are placed in rank order on the HMSA Placement Opportunity List (HPOL). The HPOL serves as the Department's official placement list of NHSC providers within each State.

Prior to actual assignment of an NHSC provider in a given HMSA, there must be a need/demand assessment done by the Department to ascertain that the area still requests health providers, the dedesignation threshold has not been exceeded, the community or entity has made unsuccessful attempts to recruit health providers on their own, and there are reasonable prospects for sound financial management of the operation to support NHSC providers being assigned to the area.

The differences between areas or communities are real and can be quantified based on the above criteria and Department system. The Department has built into the placement system local and State input to assure that local sensitivities are addressed.

Question: How many students with Corps obligations will the Department not use during the current fiscal year? If a student is informed the Federal government cannot use his/her services, what then happens? Is the student given an opportunity to enter the following year's pool or is repayment requested? What is the average repayment requested and how long does the student have to comply?

Answer: The NHSC program plans to use all NHSC scholarship recipients during the fiscal year that they become available for service. Scholarship recipients who fail to report for service are in breach of their contractual commitments. Scholarship recipients who entered into contractual agreements with the NHSC Scholarship program prior to 1978 are allowed up to three years to repay the full principal and interest due on their scholarship obligations. Scholars who entered into contractual agreements after 1978 are affected by new legislation which limits the repayment period to one year and assesses a triple penalty of the full principal and interest due on their debt. Current data show that scholarship recipients in breach are defaulting on an average of 2.5 years of service obligation with an average repayment of approximately $130,000 to $140,000 of principal, interest and penalty.

## QUESTION SUBMITTED BY SENATOR DENNIS DECONCINI

Question: I am extremely concerned about nurses whose agreements for loan repayments under the Nursing Loan Repayment Program (NLR) have not been honored. In a letter dated March 1, 1984 (copy attached), I was informed by Mr. Michael Heningburg, Director of the Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, that 115 registered nurses have requested repayments totaling $335,459 in nursing education loans under the NLR program. Of this total, 14 nurses from Arizona have applied for repayments totaling $46,096.

It is my understanding that the nurses applying for repayment submitted agreements prior to the termination of the NLR program and have completed their obligations of service in manpower shortage areas. Would you support an appropriation so that these outstanding loan obligations can be paid in full?

Answer: No funds have been appropriated or requested for the Nursing Loan Repayment program since 1981. This program repaid a portion of any type of loan which a nurse had used to finance a nursing education, if the nurse subsequently worked in a health manpower shortage area. Nurses had to apply while they were in the shortage area. If the individuals qualified, the applications were then approved and funded as appropriations became available. These applications created no binding agreement to fund an approved applicant.

Funding for this program was halted because a consensus developed in the late 1970's that offering this type of financial incentive to locate in a shortage area had little impact on nurses career decisions. And, in fact, nurses showed little interest in the program, with only 250 qualified applications received and approved during the decade the program was active. The Department continues to believe that this program is not an appropriate or effective method providing educational assistance to nurses.

At the time that the program stopped taking new applications in 1982, there were 117 approved but unfunded applications. The Department is reviewing the means available to address these applications within existing resources.

## QUESTION SUBMITTED BY SENATOR QUENTIN N. BURDICK

Question: What was the level of funding recommended by the Health Resources Administration to the Assistant Secretary for Departments of Family Practice Medicine for fiscal year 1985?

Answer: The level of funding recommended for the Family Medicine Departments program by the Health Resources and Services Administration to the Assistant Secretary was $7,800,000.

## OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

## STATEMENT OF DR. EDWARD N. BRANDT, JR., ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS AND DIRECTOR, OFFICE OF MANAGEMENT
DR. J. MICHAEL McGINNIS, DEPUTY ASSISTANT SECRETARY FOR HEALTH (DISEASE PREVENTION AND HEALTH PROMOTION)
MARJORY E. MECKLENBURG, DEPUTY ASSISTANT SECRETARY FOR POPULATION AFFAIRS AND DIRECTOR, OFFICE OF ADOLESCENT PREGNANCY PROGRAMS
DR. MANNING FEINLEIB, DIRECTOR, NATIONAL CENTER FOR HEALTH STATISTICS
JOHN E. MARSHALL, PH.D., DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES RESEARCH
DR. JOANNE LUOTO, DIRECTOR, OFFICE ON SMOKING AND HEALTH
C. CARSON CONRAD, EXECUTIVE DIRECTOR, PRESIDENT'S COUNCIL ON PHYSICAL FITNESS AND SPORTS
JOHN C. WEST, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET

### PREPARED STATEMENT

Senator WEICKER. Now we will hear from Dr. Brandt, Assistant Secretary for Health.

Dr. Brandt, if you would give us a brief summary of your statement, the statement in its entirety will be included in the record. Please introduce your colleagues and proceed.

[The statement follows:]

## STATEMENT OF DR. EDWARD N. BRANDT, JR.

I appreciate the opportunity to appear here today to discuss the budget request for the three appropriations in the Office of the Assistant Secretary for Health (OASH). The Public Health Service Management appropriation request includes funding for a number of special health programs which operate under my direct supervision and account for $94 million or 84 percent of the total request of $112 million. The remaining funds support the overall program direction of the Public Health Service (PHS). The Health Block Grant appropriation request of approximately $1.5 billion includes funds for the four block grants. Finally, we are requesting $86.4 million for Retirement Pay and Medical Benefits for Commissioned Officers.

### PUBLIC HEALTH SERVICE MANAGEMENT

As the Federal Government's primary agency in medicine and health care, the PHS goal, in concert with the private sector, is to help protect and improve the health of the American people. My job is to see that the PHS programs work as effectively and efficiently as possible toward achieving that goal. Each of the individual PHS health agencies will testify before this and other subcommittees to describe their respective plans and strategies for the upcoming fiscal ficalyear. The plans and strategies which they will describe reflect my continuing efforts to direct the program efforts and resources of PHS to focus on research, disease prevention, health protection and health promotion.

The program activities funded in this appropriation are vitally involved in both the research and prevention efforts of PHS. The two national centers, Health Services Research and Health Statistics continue to make significant contributions to PHS activities and are invaluable sources of information for PHS, the Department and other parts of the Federal government.

The National Center for Health Services Research (NCHSR) is the primary source of Federal support for research on problems related to the quality and delivery of health services. The Center seeks to create new knowledge and a better understanding of the processes by which health care services are made available and how they may be provided more efficiently, effectively and at lower cost. NCHSR research findings help in the assessment of current activities and provide information to government and private agencies on how to change or modify health programs and policies. NCHSR funds provided for the original work on Diagnosis Related Groups (DRG's), that is, the development and testing of homogeneous patient classes from the perspective of resource consumption. Congress has legislated DRG's as the basis for Federal reimbursement for Medicare patients. NCHSR researchers are currently seeking explanations for variations in the characteristics and use of hospitals, and their implications for cost, competition, technology and access. Hospitals are being examined for case-mix, lengths of stay, ancillary service use, occupancy rates and capitalization. The analyses will be essential in assessing the impact of the DRG prospective payment system.

NCHSR also supported the development of a general methodology to assess the cost-effectiveness of various health interventions.

Using this methodology, researchers concluded that the pneumonia vaccine is cost effective for improving the quality of the life and mortality of the elderly. This finding led directly to the inclusion of the pneumonia vaccine as the first and only preventive measure reimbursed under Medicare.

The budget request of $16.2 million for NCHSR will support the intramural and extramural research activities and will fund a program to disseminate the findings of health services research projects to State and local officials and program managers.

The National Center for Health Statistics (NCHS) continues to serve as the designated focal point for compiling general purpose, descriptive, national health statistics and for conducting a variety of special statistical surveys. The annual report to Congress, Health, U.S. is prepared by NCHS and includes a multitude of data which tells us where we were and where we are in terms of health status and, more importantly, helps us determine where we should be going.

The surveys supported by NCHS are in various stages which range from planning and pretesting to publication of findings. In 1985, the in-depth data analysis of the National Medical Care Utilization and Expenditure Survey will be continued. This analysis will give us a statistical base for trends and costs of health services for population groups such as the poor, elderly, and the uninsured.

The data collection phase of the Hispanic Health and Nutrition Examination Survey will be coming to an end in FY 1985 and data from earlier parts of the survey will be ready for publication by December of 1984.

The FY 1985 budget request of $42.8 million for NCHS will support continuing survey activities and will permit completion of the National Vital Statistics System. This means that the birth and death data received from all states will be in machine-readable form to enhance quality and timeliness of this phase of data collection.

We are encouraged by the preliminary findings from the Adolescent Family Life program which indicate that the projects have made significant contributions by providing care services to pregnant adolescents and adolescent mothers and by contributing to improved maternal and neonatal health outcomes. While researchers have found that pregnant adolescents and their newborns are at greater risk of experiencing health complications, most teenagers and their infants participating in this program experienced healthy outcomes. For example, both the percentages of infants born with low birth weight and of adolescents who experienced miscarriages were lower than national estimates for teenagers in 1980. In addition to assessing the medical outcomes for adolescents and their infants, the grantees are examining other program outcomes such as the impact of employment training on the level of self-sufficiency and welfare dependency.

In addition to providing care services, this program offers prevention services which are presented in several formats. Some projects offer instructions to separate groups of adolescents and parents, others work with parents and adolescents in groups, and still others offer individual and group instruction to teachers and youth leaders. Although the approach may vary, the goal of all of the prevention services is to encourage teenagers to postpone sexual involvement.

The 1985 budget request of $14.7 million for the Adolescent Family Life program will permit continuation of the FY 1984 level of effort.

Three activities within this appropriation--Disease Prevention and Health Promotion, Smoking and Health, and Physical Fitness--are essential components of the PHS prevention initiative. These programs educate the public about occupational, societal, environmental and behavioral factors which affect health. Efforts are focused on encouraging beneficial lifestyle changes through a variety of programs which include media campaigns, clearinghouses and workshops.

The Office of Disease Prevention and Health Promotion guided the development of a set of major goals for improving the health of the American people. These goals fall within 15 priority areas and include 227 measurable objectives which have been assigned to the PHS agencies based on programmatic or statutory responsibilities, experience and expertise. The FY 1985 budget request of $3.5 million for the Office of Disease Prevention and Health Promotion will enable them to monitor PHS progress toward achieving these objectives. The request also includes an increase to expand the elderly health promotion media campaign which is a community-based effort to improve the health prospects of the elderly and to reduce their burden of illness. In addition, the budget includes funds to develop the first Surgeon General's Report on Nutrition and Health to better understand this important health topic which affects every citizen.

Another activity which is an essential part of the prevention strategy is the Smoking and Health program. Smoking continues to be the major preventable cause of premature death and disability. About 300,000 deaths each year are associated with the smoking habit. While the percentage of adult smokers, 32.6 percent is at its lowest level in 45 years, 55 million Americans still smoke. The fiscal year 1985 budget request of $3.5 million would continue the public information efforts and would provide the research community with essential data on smoking prevalence. The budget also includes funds to support a review of the issue of passive smoking from a scientific perspective to more accurately determine the association between involuntary smoke exposure and its effects on health. Exercise and physical fitness has been identified as one of the 15 priority areas for improving the health of the American people. This appropriation supports the Physical Fitness and Sports activity which has lead responsibility for the objectives within this priority area. Staff support and assistance is provided to the President's Council on Physical Fitness and Sports. The Council enlists the active support and assistance of individuals, civic groups, businesses, sports groups and others to encourage regular participation in physical fitness and sports activities. The budget request of $1.4 million includes an increase to fund a National Survey of Youth Physical Fitness. This survey was last updated in 1976. The expected results of the survey would include updating the national norms used as the basis for the Presidential Physical Fitness Award.

The FY 1985 appropriation request also includes $5.8 million for the National Youth Sports program which was previously funded and administered by the Office of Community Services. The program operates through the member colleges and universities of the National Collegiate Athletic Association and offers a program of sports instruction and competition to economically disadvantaged youth.

We are requesting $18.5 million for the management and direction of the Public Health Service, an organization with resources totalling approximately 40,000 positions and an estimated budget of $8.4 billion in 1985. The 1985 request will permit this office to continue an effective overall management capability for administering PHS and OASH programs.

## GRANTS TO STATES FOR HEALTH

The 1985 request includes funding for the Preventive Health and Health Services, Alcohol and Drug Abuse and Mental Health Services, Maternal and Child Health and Primary Care block grants. The States have assumed full responsibility for three of these grants. The fourth health block grant for primary care programs was authorized through Fiscal Year 1984 but State acceptance was optional. The proposed legislation for 1985 would consolidate the community health centers, migrant health centers, black lung clinics, and the family planning programs into this grant and would eliminate after 1985 the option to receive funding for primary care services under categorical authorities. The proposed legislation also eliminates minimum state matching requirements contained in the current legislation.

The Fiscal Year 1985 funding level for the four grants is approximately $1.5 billion, an increase of approximately $32 million over the 1984 level. We are requesting that funding for these grants be included in my office in order to establish a single administrative unit for all block grants. This change is only for administrative functions. Technical and program assistance will still be provided by the appropriate agency. This administrative consolidation will streamline administrative procedures, avoid duplicative efforts, simplify State/Federal contacts, and assure maximum flexibility to the States in administering the grants.

## RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

This appropriation funds retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

The fiscal year 1985 request of $86.4 million assumes the enactment of a legislative proposal that would postpone the cost-of-living increase scheduled in May of 1984 to December of 1984 for a savings of $1.2 million. This is in accordance with a government-wide effort to contain cost-of-living adjustments for various Federal retirement plans.

The Administration is also proposing to change this account from an indefinite to a definite appropriation. As a result, the amount requested in 1985 includes a ten percent contingency margin in case of unanticipated costs.

I will be happy to answer any questions you may have.

## BIOGRAPHY OF DR. EDWARD N. BRANDT, JR.

Edward N. Brandt Jr. was sworn in May 14, 1981, as assistant secretary for health, Department of Health and Human Services. Dr. Brandt was nominated by President Reagan Feb. 13, 1981, and confirmed by the Senate May 4, 1981.

Before joining HHS, Dr. Brandt, a physician, was associated with the University of Texas. Since 1977, he had been vice chancellor for health affairs for the university system, based in Austin. From 1970 to 1977, he was dean of the graduate school, dean of medicine and executive dean of the University of Texas Medical Branch in Galveston. He had also served since 1970 as professor in the university's departments of preventive medicine and family medicine. From 1962 to 1970 Dr. Brandt was at the University of Oklahoma Medical Center, first as director of the Medical Research Computer Center and later as associate dean and associate director of the medical center.

As assistant secretary for health, Dr. Brandt directs the activities of the Public Health Service, which includes the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; and the National Institutes of Health.

Dr. Brandt provides policy guidance for other HHS health programs including the Health Care Financing Administration, which administers Medicare and Medicaid. He also maintains relationships with other governmental and private agencies concerned with health. He advises and assists the Secretary on health policy and on all health-related activities of the department.

Dr. Brandt was born July 3, 1933, in Oklahoma City, Okla. He received his B.S. degree in mathematics from the University of Oklahoma in 1954 and an M.S. degree in mathematics from Oklahoma State University in 1955. He received his M.D. in 1960 from the University of Oklahoma Medical Center and a Ph.D. in biostatistics from the same university in 1963. Dr. Brandt served his internship at the Veterans Administration Hospital in Oklahoma City and was an internal medicine resident at the University of Oklahoma Medical Center.

Dr. Brandt is the U.S. member of the Executive Board of the World Health Organization and is the U.S. delegate to the Pan American Health Organization. He has been active in various committees of the American Medical Association, Texas Medical Association and the American Association of Medical Colleges. At the time of his confirmation as assistant secretary for health, he was serving as chairman of the AMA's section on medical schools. He is also a member of the American Academy of Family Physicians' Commission on Legislation and Governmental Affairs. He has served on many boards, committees and foundations and holds memberships in a number of honorary and professional societies.

Dr. Brandt has published extensively and has made significant contributions to the professional literature throughout the entire range of health and statistical issues.

Dr. Brandt and his wife, the former Patricia Lawson, have three sons: Patrick James, Edward N. III and Rex Carlin.

October 1982

Office of the Assistant Secretary for Health
Budget Authority by Activity
(Dollars in thousands)
Public Health Service Management

| | 1983 Actual | | 1984 Request | | 1984 Appropriation | | 1984 Revised Request | | 1985 Estimate | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Pos. | Amount | Pos. | Amount | Pos. | Amount | Pos. | Amount 1/ | Pos. | Amount |
| **Public Health Service Management:** | | | | | | | | | | |
| Health Services Research | | | | | | | | | | |
| Program Operations...... | 102 | $14,829 | 107 | $16,030 2/ | 107 | $16,780 2/ | 107 | $16,888 2/ | 102 | $15,262 2/ |
| Program Support......... | 37 | 1,765 | 37 | 1,919 | 37 | 1,919 | 37 | 1,956 | 37 | 2,024 |
| Subtotal.............. | 139 | 16,594 | 144 | 17,949 | 144 | 18,699 | 144 | 18,844 | 139 | 17,286 |
| Health Statistics | | | | | | | | | | |
| Program Operations...... | 441 | 37,683 | 441 | 42,765 | 441 | 42,765 | 441 | 43,180 | 432 | 39,338 |
| Program Support......... | 62 | 3,159 | 62 | 3,356 | 62 | 3,356 | 62 | 3,416 | 61 | 3,472 |
| Subtotal.............. | 503 | 40,842 | 503 | 46,121 | 503 | 46,.21 | 503 | 46,596 | 493 | 42,810 |
| Adolescent Family Life.... | 17 | 13,358 | 17 | 16,318 | 17 | 14,918 | 17 | 14,935 | 17 | 14,716 |
| Health Initiatives | | | | | | | | | | |
| Smoking and Health...... | 20 | 2,114 | 20 | 3,521 | 20 | 3,521 | 20 | 3,535 | 20 | 3,538 |
| Disease Prevention and Health Promotion....... | 17 | 1,831 | 17 | 3,015 | 17 | 2,515 | 17 | 2,530 | 17 | 3,541 |
| National Youth Sports... | --- | 5,760 | --- | 5,760 | --- | --- | --- | 5,760 3/ | --- | 5,760 |
| Physical Fitness & Sports | 15 | 1,139 | 15 | 1,141 | 15 | 1,141 | 15 | 1,158 | 15 | 1,364 |
| Uniformed Services Univ./ Health Sciences........ | 19 | 600 | 19 | 700 | 19 | 700 | 19 | 711 | 19 | 808 |
| Subtotal.............. | 71 | 11,444 | 71 | 14,137 | 71 | 7,877 | 71 | 13,694 | 71 | 15,011 |
| PHS Management............ | 331 | 18,558 | 329 | 19,007 | 329 | 19,007 | 331 | 19,497 4/ | 310 | 18,540 |
| PHS Termination Expenses.. | --- | 1,031 | --- | 9,700 | --- | --- | --- | --- | --- | 5,000 |
| Total Obligations....... | 1,061 | 101,827 | 1,064 | 123,232 | 1,064 | 106,622 | 1,066 | 113,566 | 1,030 | 113,363 |
| Unobligated balance, start of year............ | --- | -1,064 | --- | --- | --- | --- | --- | --- | --- | --- |
| Unobligated balance, lapsing.................. | --- | +426 | --- | --- | --- | --- | --- | --- | --- | --- |
| Unobligated balance, transferred from Rural Dev. | --- | -875 | --- | --- | --- | --- | --- | -1,084 | --- | --- |
| Trust fund transfer....... | --- | --- | --- | -300 | --- | -1,050 | --- | -1,050 | --- | -1,050 |
| Total budget authority Pub. Health Service Management | 1,061 | 100,314 | 1,064 | 122,932 | 1,064 | 105,572 | 1,066 | 111,432 | 1,030 | 112,313 |

1/ Includes a proposed unobligated balance transferred from the Rural Development Loan Fund for pay raise costs.
2/ Includes transfers of $300,000 in the 1984 request and $1,050,000 in the 1984 Appropriation and Revised Request from Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds.
3/ Comparative transfer from Office of Community Services.
4/ Includes comparative transfer of $100,000 from National Institutes of Health.

|  | 1983 Actual |  | 1984 Request |  | 1984 Appropriation |  | 1984 Revised Request |  | 1985 Estimate |  |
|---|---|---|---|---|---|---|---|---|---|---|
| Retired Pay and Medical Care: | Pos. | Amount | Pos. | Amount | Pos. | Amount | Pos. | Amount | Pos. | Amount |
| Retirement payments....... | --- | $58,239 | --- | $60,046 | --- | $60,534 | --- | $60,534 | --- | $70,375 |
| Survivors' benefits....... | --- | 2,805 | --- | 2,919 | --- | 2,991 | --- | 2,991 | --- | 3,473 |
| Medical care.............. | --- | 10,281 | --- | 15,918 | --- | 10,913 | --- | 10,913 | --- | 12,600 |
| Total, budget authority Retired Pay and Medical Benefits............... | --- | 71,325 | --- | 78,883 | --- | 74,438 | --- | 74,438 | --- | 86,448 |
| Grants to States for Health: |  |  |  |  |  |  |  |  |  |  |
| Preventive health & health Services.......... | --- | 85,300 | --- | 85,300 | --- | (87,136) | --- | 87,136 1/ | --- | 89,000 |
| Alcohol and drug abuse and mental health services.......... | --- | 468,000 | --- | 430,000 | --- | (462,000) | --- | 462,000 2/ | --- | 472,300 |
| Primary care.............. | --- | 525,312 | --- | 407,312 |  | (522,120) | --- | 522,120 3/ | --- | 533,400 |
| (Community health centers)................ |  | (360,000) | --- | --- | --- | --- | (---) | (337,000) |  |  |
| (Family planning) |  | (124,088) | --- | --- | --- | --- | (---) | (140,000) |  |  |
| (Migrant health)......... |  | (38,104) | --- | --- | --- | --- | (---) | (42,000) |  |  |
| (Black lung clinics) |  | (3,120) | --- | --- | --- | --- | (---) | (3,120) |  |  |
| Maternal and child health.................. | --- | 478,000 | --- | 335,000 | --- | (399,000) | --- | 399,000 3/ | --- | 407,300 |
| In lieu of cash........... | 63 | --- | 73 | --- | (78) | --- | 78 | --- | 73 | --- |
| Program support........... | 80 | 4,117 | 80 | 4,117 | (80) | (4,117) | 80 | 4,140 4/ 5/ | 40 | 2,000 |
| Total, budget authority Grants to States for Health................ | 143 | 1,560,729 | 153 | 1,261,729 | (158) | (1,474,373) | 158 | 1,474,396 | 113 | 1,504,000 |

[1] This grant was appropriated to the Centers for Disease Control in 1983 and 1984.
[2] This grant was appropriated to the Alcohol, Drug Abuse and Mental Health Administration in 1983 and 1984.
[3] These grants were appropriated to the Health Resources and Services Administration in 1983 and 1984.
[4] In 1983 and 1984 program support was provided by the agencies to which the grants were appropriated.
[5] Includes proposed transfer of $23,000 from the Rural Development Loan Fund for pay raise costs.

### INTRODUCTION OF ASSOCIATES

Dr. **Brandt**. Thank you very much, Mr. Chairman.

I am pleased to be here today to discuss the budget request for the three appropriations in the Office of the Assistant Secretary for Health.

On my left is Mr. Wilford Forbush, who is the Deputy Assistant Secretary for Health Operations of the Public Health Service, and I think Mr. Itteilag has already been introduced.

### BUDGET REQUEST SUMMARY

The first appropriation request is for the Public Health Service management account which includes funding for two major components.

First, a number of special health programs which operate directly out of the Office of the Assistant Secretary for Health.

Second, funds to support the overall program direction of the Public Health Service.

The second appropriation request is for the health block grants and in fiscal year 1985 the request is approximately $1.5 billion.

In addition, we are requesting $86.4 million for retirement pay and medical benefits for members of the commissioned corps.

The Public Health Service has as its objective to help protect and improve the health of the American people in concert with the private sector. The job of the Assistant Secretary for Health is to see that these programs work as effectively and efficiently as possible toward achieving that goal.

Two national centers are included in the Office of the Assistant Secretary for Health: the National Center for Health Services Research and the National Center for Health Statistics, which continue to make significant contributions to our activities and are invaluable sources of information for all parts of the Government as well as the public.

As you know, the annual report to Congress, entitled Health, United States, is prepared by the National Center for Health Statistics, which serves as a designated focal point for compiling general purpose, descriptive, national health statistics as well as conducting a variety of special surveys.

Another program for which funds are requested is the adolescent family life program. We are encouraged by preliminary findings from that program which indicate that these projects have made significant contributions, both by providing care to pregnant adolescents and to adolescent mothers and by contributing to improved maternal and neonatal health outcomes.

Three programs which relate directly to the Public Health Service disease prevention and health promotion activities are the Office of Disease Prevention and Health Promotion, the Office on Smoking and Health, and the physical fitness activity. These are all essential components of our total effort.

We are also requesting in fiscal year 1985 $5.8 million for the national youth sports program which was previously funded and administered by the Office of Community Services.

Finally, we are requesting $18.5 million for the management and direction of the Public Health Service which has approximately 40,000 positions and an estimated budget of $8.4 billion in 1985.

We have also requested that the four health block grants to the States be moved to and administered by the Office of the Assistant Secretary for Health. It is important to point out that we are proposing to consolidate only the block grant administrative functions in order to simplify procedures for the States so they will have only one office to deal with. Technical and program assistance will still be provided by appropriate experts in the Public Health Service agencies.

With that summary, Mr. Chairman, I and my colleagues will be pleased to answer any questions that you may have. I have representatives from each of the program offices here with me.

### BLOCK GRANT TRANSFER

Senator WEICKER. What are you asking be transferred to your office?

Dr. BRANDT. The administrative functions of the health block grants. Three of these grants are accepted now by every State in the Union and all territories. For the fourth one, which is the primary care block grant, only the State of West Virginia and the Territory of the Virgin Islands applied in fiscal year 1983 and 1984, because of certain restrictions on that grant. However, we are proposing legislative changes which we hope will make the grant more acceptable to States in fiscal year 1985. Since three of the four grants are well established and fully operational we are just asking that the administrative functions be transferred to the Assistant Secretary for Health.

### NURSING PROGRAM

Senator WEICKER. When Dr. Graham was before us I asked the following question:

> The Institute of Medicine study on nursing recommends continued Federal support for nursing programs at a level of $80 million per year. You propose a budget of $14 million, which is a reduction of almost $38 million from the current fiscal year.

And then I also inquired as to what the amount requested for this was insofar as the request of his department. He indicated actually their request was $86 million. I indicated that I thought probably the cut came from OMB. I was told no, it did not, that apparently it was you that did it. So now maybe you would like to explain what it is you are doing.

Dr. BRANDT. Mr. Chairman, in trying to stay within the kind of budgetary guidelines that are necessary in this time of fiscal constraints, the issue was to try to address the highest priority items of the Public Health Service. We attempted to do that in the best way possible. In these restrictive times it is clear that we cannot request the kind of funding that the Institute of Medicine recommended. However, I think if you read other parts of that report you will see that we have followed precisely the priorities that were laid out by that report.

Senator WEICKER. But that's not the Institute of Medicine; it's your own people. Dr. Graham specifically said he made a request for $86 million.

Dr. BRANDT. Yes, sir. I'm aware of that. Again, the issue is that we were attempting to propose a budget that I thought was reasonable in terms of the total amount of money requested, and, at the same time support the priorities that have been established for the Public Health Service.

### BUDGET REQUEST GUIDELINES

Senator WEICKER. I don't understand. What you're saying is that you feel it is incumbent upon you to come up with the money that is going to be used for defense? What is your function here? Who are you speaking for? What are you addressing yourself toward?

I don't accept your first premise, not when you have both your department head and the Institute telling you what you need and you say "we're just going to go ahead and cut that." Where do you get your advice from? That's what I want to know. Is it based on medical fact and necessity and logic? Or are you just trying to fit in to an overall budget regardless of how that makes it impossible for you to complete the task that is assigned to you? You're not the Assistant Secretary of Defense; your job is health.

Dr. BRANDT. Yes, sir. I have nothing to do with the defense budget, but I was staying within the guidelines that I was given by my superiors.

Senator WEICKER. What do you mean by guidelines that you're getting? Who gives you the guidelines?

Dr. BRANDT. The Secretary of our Department.

Senator WEICKER. She tells you what you go ahead and do?

Dr. BRANDT. She tells me the guidelines that I'm to stay within.

Senator WEICKER. Who is telling her what to do when it comes to health matters? Is anybody able to think for themselves as to the subject matter which they are responsible for?

Dr. BRANDT. Mr. Chairman, I think the budget we have presented and the priorities that we have highlighted are quite reasonable ones.

Senator WEICKER. I didn't select Dr. Graham and the Institute certainly isn't under my direction for every piece of advice that comes in just on this one subject, and yet this goes out the window. I don't understand that. I really don't. Where are we to look for guidance in terms of matters which are very technical, very complex, which you and others have taken years as a matter of schooling and as a matter of experience to acquire that knowledge. If you're not willing to stand up and speak on it, who does? That's what I don't understand. Ronald Reagan? As far as I'm concerned, he's not a doctor or a scientist. Who does this? Edward Meese or Jim Baker? I just don't know what we are to do if we can't look to you gentlemen of the scientific and medical community for the ability to stand up and tell us what ought to be done.

Mr. ITTEILAG. Mr. Chairman, let me say something about the budget formulation process.

Senator WEICKER. I might add, this is a good example. I don't want to sit here and go through the whole damn budget. We'd be doing the same thing over and over and over again. I'm not saying that this is the only area and chewing this to death. We might as well discuss this, because whatever you are going to respond to in this area is going to apply to many others also.

### BUDGET FORMULATION PROCESS

Mr. ITTEILAG. Mr. Chairman, one important aspect of this situation is that the Secretary, with respect to discretionary programs, receives a budget target, a certain dollar level.

Senator WEICKER. Who gives them that?

Mr. ITTEILAG. It comes from a group known as the Budget Review Board.

Senator WEICKER. Who is on that?

Mr. ITTEILAG. That board consists of Mr. Stockman, Mr. Meese, and Mr. Baker.

Senator WEICKER. Dr. Stockman, Dr. Meese, and Dr. Baker, right? [Laughter.]

Mr. ITTEILAG. That type of budget target is provided to all department heads, and we are asked to submit a budget consistent with that target. The Secretary in turn chose to ask her operating division heads to submit a budget to her——

Senator WEICKER. Dr. Heckler. [Laughter.]

Mr. ITTEILAG [continuing]. Within their share of that target. And it is in that manner and with that sort of overall ceiling that the budget is formulated. We are happy to respond and we have responded to the House with respect to what the professional judgment of the experts who come before you is, and I am sure Dr. Brandt would be happy to do that. And I think it's in that manner that we can get a reasonable dialog on the record on these subjects. But Dr. Brandt was operating within the groundrules of the Secretary, and the Secretary was operating within the groundrules of the Budget Review Board.

Senator WEICKER. You're giving an honest answer, and that's what upsetting me. Your answer is candid, it's honest, and that is what is upsetting to me.

Even though I sit at the head of this committee, I really seek out the advice of those that have the expertise, and it would just be unparalleled conceit on my part as a BA and an LLB to go ahead and impose my will on matters that are entirely out of my ken. And yet that apparently is what is done in the formulation of this budget, which is so instrumental, so key to the health and safety of the citizenry as a whole. It really is appalling.

Dr. Brandt, are you in the medical science field? Is that your background?

Dr. BRANDT. Yes, sir, I am a physician and have spent my entire life in medical education.

Senator WEICKER. You were the dean of what?

Dr. BRANDT. The Texas Medical School.

Senator WEICKER. Here we bring a man like you with a background like that into this position, the highest qualifications possible—maybe secondary to Yale, but that's all right. [Laughter.]

Is Dr. Graham also one that comes from the scientific or medical field?

Dr. BRANDT. Yes, he is also a physician.

Senator WEICKER. That's a waste of talent.

All right. Let's get to some specific questions.

### USER LIAISON PROGRAM

The Appropriations Committee report in fiscal year 1983 and again in fiscal year 1984 clearly stated the congressional intent that the user liaison program of the National Center for Health Services Research be strengthened. In fact, Congress provided an additional $500,000 in fiscal year 1984 specifically for that purpose. Yet I received a letter from Gardner Wright, Representative Wright, the chairman of Connecticut's Commission on Hospitals and Health Care, which states that the funds allocated to the user liaison program may actually have been reduced from the fiscal year 1983 level.

Why have you reduced the funding for the user liaison program?

Dr. BRANDT. I wasn't aware it had been reduced.

Dr. Marshall, can you speak to that?

Dr. MARSHALL. Yes, sir, I can speak to that.

It is true that one portion of the user liaison program in fiscal year 1984 was reduced from the 1983 level, and that is the amount available for external contracts. However, the program was strengthened in other ways, and the fiscal year 1983 level was well above the 1982 level. Congress did appropriate some additional funds for the National Center, but it specified that they could be used for three purposes. The user liaison program was one of those activities. The others had to do with making medicare reimbursement recommendations with respect to coverage for new technology under medicare, and the third had to do with increasing the amount of research that we were doing on issues that looked at how you could save money in the medicare trust fund system without unduly penalizing or shifting the burden to the beneficiaries. And so we had to spread that money among several different accounts.

But I believe the user liaison program is adequately funded when you look at it in the context of our other responsibilities, foremost of which is to support or investigate research programs in health services research.

Dr. BRANDT. It is clearly a very good program and I would hope the people you hear from would also agree that it is effective in its activities.

### DISEASE PREVENTION INCREASE

Senator **Weicker**. You are requesting an increase of $1 million for health promotion and disease prevention. How will this increase be used?

Dr. **Brandt**. There are a number of ways that we intend to use that money. One is to expand our current program of cooperative agreements with non-Federal agencies and organizations. We are requesting an increase of $240,000 to fund four additional cooperative agreements, for a total of 11 agreements in fiscal year 1985. The new agreements will focus primarily on nonhealth related organizations, such as the National Parent-Teachers Association and others, to try to stimulate health promotion in the schools.

We intend to expand the national elderly health promotion media campaign, which was initiated this year, to try to encourage elderly people to identify those health risks that they may have and try to deal effectively with them. This effort is coordinated with the National Institute on Aging.

In 1985 we propose to produce for the first time, a Surgeon General's report on nutrition and health, the purpose of which will be to try to summarize available information about nutrition and to capture the current state of scientific understanding.

We intend to put additional money into the National Health Information Clearinghouse.

Finally, in 1985 we propose to expand our monitoring capabilities for the 227 measurable health objectives that we are seeking to attain by 1990.

### PASSIVE SMOKING STUDY

Senator **Weicker**. You're requesting $500,000 for a passive smoking study. What is that?

Dr. **Brandt**. As you know, there has been a lot of debate, Mr. Chairman, over the issue of whether or not nonsmokers are affected by being exposed to cigarette smoke from others smoking in an area. There have been some scientific disagreements, not to mention other kinds of disagreements, over this issue. What we are attempting to do with this study is to compile all of the available information on the whole issue of passive smoking, try to identify the risks that nonsmokers, in particular, are exposed to, and identify any further areas of research that are needed.

Senator **Weicker**. I'll save you 500,000 bucks. I used to smoke two packs of cigarettes a day up until about 1971. I stopped because I'd usually have about two or three bouts of bronchial pneumonia. I stopped, and that was the end of the bronchial pneumonia.

I can tell you one thing right now, even 13 years later, if I sit in a room with people smoking, the first place I start to get irritation is in my bronchial tubes. There is no question in my mind as to what is causing it. I don't think you have to spend $500,000 to find out that people very definitely are affected by other people's smoke. It's no big deal. I don't go around telling people to put out their cigarettes, but I'm just saying to you that I don't think we have to spend another $500,000. Maybe what we ought to do is to get out of this whole business. If we want money, if this administration wants money, let's get out of the business of tobacco period. Let's just get out of it.

Dr. BRANDT. I agree with you that the case is very solid on passive smoking, but in view of the number of requests and the number of issues that come up with respect to local governments that are attempting to pass legislation, it is necessary to compile what is known and what isn't known about this subject.

### ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

Senator WEICKER. How much financial support is provided to adolescent family life demonstration projects from non-Federal sources?

Dr. BRANDT. Non-Federal sources are required to provide increasing levels of matching dollars throughout the project period. The total amount in 1983 was 41 percent which exceeds the minimum required match of 30 percent during the first 2 years. By the fifth year of the project the minimum match rises to 60 percent.

Senator WEICKER. Can you give us the names of some of the major sources of non-Federal funds?

Dr. BRANDT. Yes; State funds are one of the sources of funds. Mrs. Mecklenburg is here and she can give some other examples.

Mrs. MECKLENBURG. There are county funds and State agency funds. AFL demonstration projects are cooperative projects where not only the Federal funds are used, but also local community funds. There are also private foundations which have taken a great interest in some of these projects, and local foundations are providing more funding for these efforts.

So we are very excited to see the diverse sources of funding and interest by various organizations in the projects.

### DISTRIBUTION OF FAMILY PLANNING RESOURCES

Senator WEICKER. This is a question that I had asked previously. Apparently you're the one, Dr. Brandt, better qualified to respond to it. Congress provided almost $16 million more for family planning in fiscal 1984 than the previous fiscal year. Yet we are hearing that some of our regions, including my own region I, initially get less money in 1984 because you are setting aside $500,000 in each region for national priorities programs. What are these national priorities and how did you arrive at the figure of $500,000 per region, or $5 million for the whole country?

Dr. BRANDT. Title X mandates that certain kinds of activities be carried out as a part of that program, because family planning is more than just contraception. One of those activities, for example, includes infertility services to be provided to people who are having difficulty having a child. The second of these activities involves the whole issue of natural family planning techniques, that is, nonpharmacological, nondevice issues.

We held meetings in every region with family planning providers to get their views on a variety of topics. It was very clear that some of these providers were having some difficulty in organizing services in such areas as infertility and natural family planning. It was decided that we would, in fact, allocate specific funds to each region for the purpose of permitting innovative approaches to solve these problems, and the figure of $500,000 was determined. That's in keeping with previous years' practice of reserving and allocating between $4 million and $5 million for special projects to be carried out. Fiscal year 1983 was a year in which that had not been done.

The allocation formula this year was based upon the usual factors except we put more emphasis on stability of funding.

What happened to your own region was the fact that the percentage of women in need fell. This was the first year that we had solid figures from the 1980 census and from other sources that would allow us to obtain better estimates of what those figures are. In region I the percentage of women in need decreased, and in fact the percentage of women who received services decreased. So it was more than the decrease in the population in need. The same situation was true also of region II. Other regions had higher percentages.

Senator WEICKER. Region I includes what?

Dr. BRANDT. Region I includes Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.

Senator WEICKER. What does region II include?

Dr. BRANDT. New Jersey, New York, Puerto Rico, and the Virgin Islands.

Senator WEICKER. And the need went down in those areas?

Dr. BRANDT. The percentage of the total women in need decreased in those two regions. These are women in their reproductive years who are at risk of unintended pregnancy at or below 150 percent of the poverty line. However, with $500,000 being allocated to every region, both region I and region II will be increased over their 1983 funding level.

Senator WEICKER. If you're talking about Boston and New York and Hartford, Newark and all the rest, I find it very hard to believe those statistics.

Dr. BRANDT. We will be happy to send you the data.

Senator WEICKER. I would like to have that data.

Dr. BRANDT. Fine. We will be happy to do that.

[The information follows:]

## WOMEN IN NEED STATISTICAL DATA

Of the total number of women-in-need (WIN) in the Nation, the number in region I decreased from 5.1 percent to 4.6 percent. Of the total number of WIN in the Nation who received title X family planning services, the number in region I decreased from 5.2 to 4.8 percent. In region II, WIN decreased from 10.7 percent to 10.6 percent and WIN served went from 9.5 percent to 7.6 percent.

### FORMULA ALLOCATION

Dr. **Brandt**. As you know, in the Department evaluation funds are reserved from program funds and then after the requirement for evaluation money is determined funds are made available to the program. In the very near future we will be allocating additional funds to the various regions to go back into the service programs.

The concept behind the formula allocation is, in fact, a reasonable one. That is, those areas of the country that have a larger percentage of women in need should get the largest percentage of funds appropriated. Similarly, we include a performance characteristic in the allocation formula so that those regions which in fact serve a higher percentage of these women in need get greater funding. It is those two factors that are major components of the allocation formula.

### HEALTH TECHNOLOGY ASSESSMENTS

Senator **Weicker**. Dr. Arnold Relman, editor of the New England Journal of Medicine, recently expressed concern that $5 to $10 billion a year is being wasted on useless or dangerous medical technologies and almost as much on marginal ones not worth what they cost.

What activities to assess health technology are planned by the National Center for Health Services Research in 1985?

Dr. **Brandt**. There are two principal activities. We will continue our extramural grant program for the purpose of developing methodology for the evaluation of technologies, and second, we will continue to conduct technology assessments at the request of the Health Care Financing Administration to determine coverage under medicare.

Dr. Relman hits upon an important point, and that is that the whole issue of technology assessment in this country is not done very well. The Federal Government has never done all of the technology assessment and, in my view, shouldn't do all of the technology assessment that needs to be done.

We have been exploring this issue with the Institute of Medicine, and have supported a study to look at the whole issue of technology assessment. They have now sent a report which in effect recommends that a private entity be established, perhaps within the National Academy of Sciences to which all relevant bodies would contribute, pay, and assist in establishing priorities and provide policy direction for the process of evaluating technologies.

I don't have any way to question or agree with Dr. Relman's figures as to the amount of money, but there is very little question that technology assessment is not handled well in our society. Recommendations to the Health Care Financing Administration for coverage of certain technologies under medicare, which is our responsibility to do, is done well by the PHS staff.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Weicker**. I have other questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### CUTTING UP HEALTH RESOURCES

Question: We are pretty shocked at what you are trying to do to the Health Resources and Services Administration. Your budget request is for $271.9 million, an 81% cut from the fiscal 1984 appropriation of $1.4 billion. In furtherance of whatever you're trying to achieve, you would transfer big block grants and make program and staff cuts. Health Resources and Services has been doing an excellent job, as far as we can tell. Why change things now? What's the problem? The Assistant Secretary for Health has always had policy control over the Health Resources and Services Programs, no matter where they're located. Why do you have to have them sitting in your lap to do the job?

Answer: The 1985 budget proposes that funding and administrative support for the four health block grants be included in the Office of the Assistant Secretary for Health. This arrangement would provide a single point of contact for the States and would streamline administrative procedures. We are proposing this change now because three of these grants have completed their transition period and are fully operational. In addition, States have developed administrative systems for the operation of block grants and now require minimal Federal assistance.

The Office of the Assistant Secretary for Health will be responsible for only administrative functions which are limited to reviewing grant applications, distributing funds according to formula, and reviewing State reports. Technical assistance and program consultation required by the States would still be provided by the appropriate PHS agency.

### BLOCK GRANT INCREASE

Question: I was pleased to note that this year the Department is requesting roughly a 2% increase in funding for the Block Grants to the States. Last year, as I recall, the increases provided were Congressional initiatives. Why did the Department seek an increase and what do you feel it will accomplish? As you know there is much talk of spending freezes. Do you feel this would be counter-productive to your objectives?

Answer: The block grant funding mechanism is an important part of the Federal government's public health effort and it is essential that services continue at a fairly constant level. The requested increase reflects the priority granted to the block grants. The imposition of spending freezes would severely restrict management flexibility to address the changing requirements of an organization. Support for the FY 1985 President's Budget as proposed is preferable to spending freezes.

### NCHSR - BUDGET REDUCTION

Question: Your budget justifications indicate that the National Center for Health Services Research is requesting $1.6 million and 5 positions less than the $18.9 million appropriated for FY 84. How do you plan to absorb this cut in funding and positions?

Answer: The decrease of $1.6 million reflects a reduction for new extramural grants and costs associated with the reduction of 5 positions.

The FY 1985 budget request will provide funding for approximately 11 new investigator-initiated grant applications compared to 21 new grants in FY 1984. These new grants will address research areas such as: technology assessment, health promotion and primary care. Ongoing intramural and extramural research areas and dissemination activities will continue to be funded.

## TERMINATION EXPENSES

Question: Will you explain why you are requesting $5 million in termination expenses. How many employees will be terminated? What programs will be affected by terminations?

Answer: The funds are required for two months salary costs of positions proposed for elimination, estimated severance pay and unemployment compensation for separated employees and residual overhead expenses. The positions to be eliminated are associated with the expansion of the primary care block grant which will reduce categorical program responsibilities, the phase-out of the health planning program, a reduction in the health professions program, and a reduction in related program management functions. For those employees whose positions are eliminated, every effort will be made to locate jobs for them within the Department as well as outside the government. The number of employees ultimately terminated will depend on the rate of voluntary attrition and the success of placement efforts. The estimate of $5.0 million is based on there being fewer than 100 involuntary separations resulting from the elimination of approximately 500 positions.

## NCHSR - USER LIAISON PROGRAM CONTRACTS

Question: Could you tell me the amount of dollars allocated to contract activities of the NCHSR User Liaison Program in FY 1983 and 1984, as well as the amount of the Administration's FY 1985 budget that will be allocated to NCHSR User Liaison Program contract activities?

Answer: Contract activities for the User Liaison Program were funded at $453,000 in FY 1983. The targeted funding level for FY 1984 is $430,000. For FY 1985 contract support is planned at a level of $260,000.

## NCHSR - HEALTH PROMOTION/DISEASE PREVENTION

Question: What contribution has NCHSR made to the Department-wide health promotion and disease prevention efforts?

Answer: The National Center for Health Services Research (NCHSR) has Health Promotion and Disease Prevention (HPDP) as one of its priorities. This encompasses health status measurement; organization and provider studies; analysis of public and private program interventions; and consumer knowledge, attitudes and behavior. The following are examples of HPDP research conducted and supported by NCHSR during 1983:

- NCHSR contributed support to a conference in October 1983 entitled "Health Promotion and Disease Prevention for Children and the Elderly: Major Research issues for the 1980's" for future development of an HPDP research agenda.

- The User Liaison Program held two meetings to help develop research strategies in areas cited as critical by State and local policymakers. HPDP interest encompassed elderly, infants and children and low income groups.

- Extramural research projects underway include preparation of an evaluation HPDP monograph to emphasize the analysis of preventive medical care and an investigation of whether incentive and skill training in counseling for physicians can result in cessation of smoking by patients.

- Also, NCHSR's intramural staff is providing technical and substantive input for the improvement of the Health Risk Appraisal System of CDC and a health status index developed at NCHSR is being applied in the Health Risk Factors Survey by CDC to measure the health status of communities with varying prevalence rates of health risk factors.

## NATIONAL CENTER FOR HEALTH STATISTICS

Question: Your budget request indicates a decrease of $3.8 million and 10 positions for the National Center for Health Statistics. What program areas are affected?

Answer: The proposed changes in the programs are as follows:

-- Survey changes for periodicity........... -$5.5M
Hispanic Health and Nutrition Examination
Survey-completion of data collection
(-$4.7M)
National Health and Nutrition Examination
Survey (+$.9M)
National Ambulatory Medical Care Survey

-completion of data collection(-$.7M)
National Nursing Home Survey - completion
of data collection (-$1.6M)
National Master Facility Inventory (+$.6M)

-- Increase for National Vital Statistics System................................. +$.9M
To complete the collection of birth and demographic death data in machine readable form in all states and to expand the system for medical data on death.

-- National Health Interview Survey........ +$.8M
For recruitment and training of interviewers employed by the Census Bureau and mandatory increases for the Census Bureau.

Question: What is the status of the National Vital Statistics System? How do you plan to use the additional $871,000 in your request? When do you expect to complete this system?

Answer: We have developed a plan which would permit NCHS to complete the coverage of this program by the end of FY 1987. At that time, we would have funded contracts with all 54 States and registration areas for births and demographic death data in machine readable form. The requested increase of $871,000 in FY 1985 will enable NCHS to complete the automated system for births and demographic data on deaths and to expand the system for collecting medical death data. This plan assumes the inclusion into the system of States and registration areas as follows:

| | Current | FY 1985 | FY 1986 | FY 1987 | Total |
|---|---|---|---|---|---|
| Birth and demographic death data | 48 | 6 | 0 | 0 | 54 |
| Medical data on death | 16 | 4 | 11 | 0 | 31 |
| Marriage data | 12 | 0 | 17 | 17 | 46 |
| Divorce data | 8 | 0 | 12 | 11 | 31 |
| Induced abortion data | 15 | 0 | 0 | 9 | 24 |

The 31 registration areas for medical death data represent data for about 80 percent of all deaths. For the remaining 20 percent, it would be more cost effective for NCHS to process the data on microfilm rather than having the States change their processing procedures. Eligibility for the marriage, divorce, and induced abortion subcomponents is determined by the establishment of central State files meeting NCHS specifications.

Question: Why are you requesting appropriations language to have funds from the sale of data tapes credited to this account with no Fiscal year limitation? How much do you expect to collect in FY 1985? How do you plan to use this money?

Answer: The appropriation language we have requested is as follows: "and, in addition, amounts collected by the National Center for Health Statistics from the sale of data tapes shall be credited to this appropriation and shall remain available until expended".

Without this provision, funds collected near the end of a fiscal year could lapse and not be available for the activities for which they were collected, i.e., to support the production of more data tapes. We expect to collect approximately $200,000 in FY 1985.

Question: Why are you decreasing support for the Hispanic Health and Nutrition Examination Survey? How are you planning to use the funding in this study.

Answer: The field work for the HHANES will be completed at the end of the first quarter of FY 1985. The request therefore, reflects this decrease in the resources that will be required to support this survey as it moves into the less expensive data analysis, processing, and data dissemination phase.

Question: The National Survey of Family Growth was last conducted in 1982. I understand that it should be scheduled to be repeated in 1986. If this is true, shouldn't you be requesting planning funds in your FY 1985 budget? Are you planning to conduct this survey in 1986?

Answer: As originally scheduled, the survey was to have taken place in FY 1986. However, the 1985 budget only contains funds for analysis and dissemination of data collected in previous surveys. The Cycle IV NSFG is now scheduled to be conducted in 1987.

## ADOLESCENT FAMILY LIFE

Question: Last Year you responded to my question concerning requested results of the Adolescent Family Life Project Grants by saying it was too early in the process to expect results. Once again, can you report to us any results supported by the Adolescent Family Life Project Grants?

Answer: The Adolescent Family Life (AFL) projects are multi-year programs and, while projects have their service delivery systems and evaluation plans in operation, the data that are available are still preliminary. The findings from the projects' first year of operation suggest that some of the adverse outcomes of teenage pregnancy can be alleviated through a variety of service delivery modes. Adolescents and their infants participating in AFL programs experienced a significantly lower infant mortality rate compared to the 1982 infant mortality rate for all women; a decrease in the percentage of infants born with low birth weight as compared to the national estimates for teenagers in 1980; and a decrease in the percentage of adolescents who experience miscarriages as compared to the national estimates for teenagers in 1980.

Preliminary data from AFL research projects suggest that their final reports will be helpful to policy makers, service providers, and the general public. For example, one AFL project is analyzing interviews with adolescents and their parents from a national sample to explain why some adolescents but not others become sexually active. This project has indicated that family characteristics have a central role in the explanation of adolescent sexual activity; for instance, adolescents who live with, or frequently visit, both of their biological parents are much less likely to have had intercourse by the age of 15 or 16. A study of the attitudes and knowledge of adoption among pregnancy counselors shows that while counselors believe adoption is advisable for many pregnant teens, they know very little about adoption and often do not discuss this option in their counseling sessions. Another study on improving parenting skills shows that many adolescent mothers do not have the mental maturity to grasp and implement the parenting training which a program may offer.

While the preliminary findings are encouraging, projects must be in operation for three to five years before final evaluations and reports can be completed. At that time, effective model programs will be well documented for States and communities to adopt and our knowledge of the causes and consequences of adolescent pregnancy will be greatly enhanced.

Question: As you know, the ACLU is challenging the Adolescent Family Life program on the grounds of church and state. What steps did you take in making grant awards to insure that no specific religious values would be promoted? How are you monitoring the implementation of the projects to protect against the promotion of any particular religious teaching?

Answer: Since this matter is currently in litigation we have been advised not to respond to these questions at this time.

Question: One of the goals of the Adolescent Family Life program is to encourage pregnant teenagers to carry their pregnancies to term and then to place the infant for adoption. How are you implementing this?

Answer: The Adolescent Family Life (AFL) program is promoting adoption as an option for adolescent parents through the provision of educational, counseling and adoption services to pregnant adolescents and adolescent parents in demonstration projects. AFL grantees present adoption information and discuss the adoption option with pregnant adolescents and adolescent parents in order to assist them in selecting a course of action. We anticipate that when adolescents have an opportunity to become better informed about the adoption alternative, a greater number will select adoption.

Question: I understand that some of the proposals set specific targets in terms of the number of adoptions to be achieved. How can we be sure that the rights of the young mothers are not being violated in these projects?

Answer: One of the best safeguards to assure that the rights of young women are not being violated in the decision making process is the requirement in the Adolescent Family Life Act that parents give consent for the services provided their children by the projects.

Question: It has been about eight months since the Department issued proposed regulations for this program. When may we expect the final regulations?

Answer: The period for public comment on these regulations is now over and my staff has analyzed the response. A final rule is being drafted.

Question: I understand that the Adolescent Family Life Program supports projects designed to prevent sexual activity among adolescents. What evidence do you have that the prevention projects are actually successful in deterring sexual activity?

Answer: Preliminary results from individual prevention projects are encouraging. One project which offers a family-centered curriculum reports increased parental involvement, strengthened family ties, and less permissive sexual attitudes among adolescents. Another project which provides an education program on sexuality, decision-making, and family interaction to parents and adolescents finds significant positive changes in basic knowledge of sexuality. In another project, adolescents, after completing a six-week curriculum, showed improved communication skills and self-esteem and felt more comfortable discussing sexuality with their parents, who, in turn, showed improved self-esteem and felt more comfortable about their familial roles and ability to communicate with their children.

These findings from the projects' first year of operation suggest that progress is being made within AFL projects.

Question: The Adolescent Family Life program stipulates that 1-3 percent of the appropriated funds shall be used for evaluation. Who is conducting that evaluation? What kinds of information will it provide? When will a report be forthcoming?

Answer: Individual program evaluations will be conducted by an organization or entity which is independent of the grantee. To assist in conducting the required evaluations, Title XX requires the grantees to develop a working relationship with a college or university located in the grantee's State which will provide, or assist in providing, monitoring and evaluating their services. In addition to these individual evaluation efforts, a cross-cutting evaluation design which measures and compares the relative effectiveness and efficiencies of the various models is being tested. Initial funding for the demonstration projects was provided in September 1982 with project periods of three to five years. Final evaluation reports will be prepared when the project periods are completed.

Question: How do you plan to evaluate and disseminate all the information gathered from the Adolescent Family Life (AFL) research and demonstration projects?

Answer: Legislation requires an individual evaluation of each project and that all grantees establish working relationships with colleges or universities in their states for the monitoring and evaluation of project services. In addition to these individual evaluation efforts, a cross-cutting evaluation design which measures and compares the relative effectiveness and efficiencies of the various service models is being tested.

Initial funding for research and demonstration projects was provided in September 1982 and final results of these programs will not be available until the projects are completed. However, we have already initiated a major dissemination activity. We have set up a data archives, where data on adolescent pregnancy and pregnancy prevention are deposited and are made readily available to anyone interested in these issues. When AFL research grants are awarded, we require that public use data tapes be placed in a data archive within 18 months after the end of the study. Other plans for dissemination include the use of public media resources that are often available without charge. For example, communication channels such as professional journals, public forums and meetings, community newsletters and publications of state and local organizations with special interests in adolescent pregnancy will be utilized. Program funds will be used only to facilitate this strategy or to supplement these channels if they prove inadequate to the task.

Question: How many grants are serving minority populations?

Answer: Since its inception the Adolescent Family Life Program has been very involved in providing services to minority adolescents. Although 1984 grants have not yet been awarded, 29 of the 59 projects funded in Fiscal Year 1983 served clientele in which the proportion of minorities was 50 percent or more.

Question: What percentage of the funds allocated to the grant and project budget go to minority grantees?

Answer: Of the total funds awarded for demonstration projects, $5.6 million or 64 percent was awarded to grantees serving clientele that was more than 50% minority.

## SMOKING AND HEALTH

Question: You are requesting $500,000 for a passive smoking study. Can you more fully describe "Passive Smoking" and why this study is important?

Answer: The past several years have been marked by increased public attention to the question of passive smoking. This has resulted in a wide response by local and State governments and by private employers and merchants in establishing policies to address this issue. Numerous surveys have shown that people exposed to cigarette smoke report eye irritation, headache, nasal symptoms and cough. Obviously, passive smoking is annoying and discomforting to many people, but there are more compelling reasons to examine this issue.

The Public Health Service reviewed the health significance of passive smoking in detail in its 1979 Report on the health consequences of smoking, this and more recent information establish the following:

1. Some of the potentially dangerous ingredients in cigarette smoke are present in greater quantities in sidestream smoke than in mainstream smoke. Levels of cigarette smoke constituents, including carbon monoxide, can be reached in cigarette-smoke-filled rooms which may adversely affect the very large numbers of men and women, many of them elderly, who suffer from chronic lung disease or cardivascular diseases.

2. Passive smoking can exacerbate the symptoms of asthma and chronic bronchitis.

3 In addition to the effects of involuntary smoking on people with existing disease, recent studies suggest that passive smoking may contribute to disease in health nonsmokers. Recent studies have reported an increased risk for lung cancer in nonsmoking wives of smoking husbands ... and even though the nature of this association is not resolved, it does raise concern that passive smoking may pose a carcinogenic risk to the nonsmoker.

A passive smoking study is important to clarify and amplify the facts surrounding the involuntary smoking issue.

Question: Anti-smoking activities have been a priority for some time. Are you satisfied that the results of these activities have been worth the time, effort, and financial investment?

Answer: In all respects, the Federal investment in anti-smoking efforts is highly satisfactory.

Significant progress has been made:

-- Per Capita consumption of cigarettes is at its lowest level since the late 1940's. Last year alone, Americans smoked 30 billion fewer cigarettes than the previous year.

-- The proportion of Americans who are current smokers has declined to less than one-third of adults. In 1965 the proportion who were regular smokers was 42 percent.

-- Cigarette smoking among adolescent boys is probably lower today than at any time since the 1920's or 1930's and smoking among adolescent girls, which had been increasing during the early 1970's is also declining.

-- Over one-half of all cigarettes smoked today yield less than 15 mg of tar.

-- Coincidental to these declines in overall cigarette smoke exposure the mortality from cardiovascular disease, particularly coronary heart disease -- the number one cause of death in the U.S. -- has been steadily declining.

-- Lung cancer mortality among younger age groups of males has declined. These males have smoking prevalence rates substantially lower than older males.

Professor Ken Warner of the School of Public Health, University of Michigan estimated that due to the smoking control measures found in this country, an estimated 200,000 people are alive today who would not have been had these public health measures not been taken. As we experience further declines in the smoking prevalence rate (estimated to be less than 30 percent by recent surveys), further health gains will be realized by our population.

## HEALTH PROMOTION/DISEASE PREVENTION

Question: You are requesting an increase of $1 million for Health Promotion and Disease Prevention. How will this increase be used?

Answer: Health promotion and disease prevention activities are important in improving the health of individuals in this nation and play a critical role in reducing rapidly increasing health care costs.

The FY 1985 increase of $1.0 million will be used to support development in several major program areas.

- o Fund four additional cooperative agreements (+$240,000)
  A total of 11 agreements with major national organizations will be funded to stimulate effective health promotion efforts. Emphasis will be placed on non-health related organizations such as the National Parent Teachers Association.

- o Expand National Elderly Health Promotion Media Campaign (+$333,000)

  This community-based campaign was initiated in FY 1984 and will alert the elderly about health risks specifically related to them and encourage them to seek beneficial information. The effort is coordinated with the National Institute on Aging, the Administration on Aging and the American Association of Retired Persons.

- o Develop first Surgeon General's Report on Nutrition & Health (+$150,000)
  This report will help capture the state of scientific understanding on nutrition, a subject affecting every citizen, and offer a series of findings and recommendations for National efforts in Nutrition Education, Nutrition Services, and Nutrition research and monitoring.

- o Increase for the National Health Information Clearinghouse (+$110,000)
  The Clearinghouse is the major vehicle for facilitating and coordinating PHS efforts to provide health information to the public. The NHIC responds to the demands for information which increase about 30% per year. The level is currently about 2,500 calls per month, with as many as 6,000 callers getting busy signals because of inability to meet demand.

- o Expand the prevention monitoring capabilities (+$150,000)
  The data tracking system to provide stronger prevention monitoring capabilities will be completed, scientific support and technical assistance activities increased, and in FY 1985 a mid-course review of national progress toward the 1990 objectives will be undertaken.

The requested increase also includes $28,000 for pay raise and within grade increases.

Question: Why are you requesting an increase for "Cooperative Agreements"?

Answer: Our cooperative agreements are designed to assist non-Federal agencies with health promotion projects of mutual interest to the Federal government and the agencies. The cooperative agreement mechanism is used because it allows close cooperation, technical assistance, and continued interactions. Funding is not a procurement but a form of financial assistance with substantial programmatic involvement by the Government. Formal agreements allow a consistent and reinforcing message to be developed by the national organizations which act as resources for health promotion programs at the local level.

Thus, for a small dollar investment (approximately $60,000 per agreement), the Federal government is in a position to influence large numbers of people who are affiliated with these national organizations. In order to influence a wider range of individuals at the local level, the four new agreements will focus on national organizations that can reach populations at schools, in the community-based settings, at the worksites, and in the clinical treatment settings.

Question: What is the purpose of these agreements?

Answer: The purpose of the cooperative agreements with voluntary groups is to integrate health promotion programs into the ongoing services and operations of each of the organizations and in that way provide a wider range of health promotion programs at the community level than is currently available. To accomplish this, during the first year of the cooperative agreement each of the organizations surveyed its affiliates to identify existing programs and materials and to ascertain the needs within the organization for health promotion programs. In the second year, each began to disseminate health promotion information to its affiliates through newsletters, special conferences and materials.

In addition to these activities, each has identified at least one special project to meet the needs of its organization. These special projects are being operated and assessed this year. The National Urban League is testing a program designed to educate young, black pregnant women about nutrition and health care during pregnancy. The YMCA is developing family oriented health promotion materials to be used at Y family camps throughout the country. COSSMHO is using Philadelphia as a test site to determine how best to bring health promotion services to Hispanic communities. The American Red Cross which already has developed many program models is enhancing its technical capability of making program information available throughout its system. The four agencies meet regularly to exchange information and ideas and identify common interests.

The agreement with the Washington Business Group on Health (WBGH) is intended to increase the number and quality of worksite health promotion programs by expanding the awareness and knowledge of corporate decision-makers. To achieve this goal, the project will increase the amount of high quality, meaningful information on worksite health promotion programs available to the media that is read and respected by corporate decision-makers. Specifically, the WBGH will: establish an information system to collect and package influential information about worksite wellness programs for corporate decision-makers; develop a communication system to inform media correspondents and editors of the information collected and assist them in incorporating this information into their work; and establish an ongoing dialogue on media issues among national organizations that share the objectives of increasing the number and quality of worksite wellness programs.

## COST OF LIVING ADJUSTMENT

Question: Your budget request for retirement pay assumes legislative approval of a delay in cost-of-living adjustments. Will you send an amended request if Congress does not delay the COLA?

Answer: If the delay in the COLA is not approved, it would probably not be necessary to submit an amended request. The budget request includes a 10 percent reserve of $7.9 million. Savings from the COLA delay are estimated to amount to approximately $1.3 million which could be offset against the reserve.

## NCHSR - STATE AND LOCAL RESEARCH NEEDS

Question: I understand that in March 1983, NCHSR convened two groups of state and local officials for the purpose of developing "research strategies" that would "address some of the critical health care delivery policy issues and operational problems facing state and local governments". Given this effort, could you provide the Committee with a description of the specific actions that you plan to take as a result of these meetings to stimulate new grants or contracts that address the research needs identified by the state and local participants? I'd be particularly interested to know whether any new grant or contract solicitations will be developed in concert with state and local officials as a result of this effort.

Answer: Research needs identified by State and local participants covered the broad range of research topics supported by NCHSR e.g., health promotion and disease prevention, long-term care, health care financing, insurance and regulation, and modeling for analytic tasks.

Therefore, solicitations are not necessary to generate research proposals in these areas. Rather, NCHSR will continue to fund high quality research which is investigator-initiated through its extramural research grant program.

Additionally, analyses of critical health care delivery policy issues produced by NCHSR's intramural researchers are made available to State and local users.

## NCHSR - BUSINESS COALITIONS

Question: Can you tell the Committee whether NCHSR has given any thought to devising ways to provide assistance to the rapidly developing "Business Coalitions", whose principal aim is to find ways in which the business community can act to control the rapidly rising costs of health care?

Answer: In FY 1983, NCHSR recognized the increasingly important role that business coalitions are playing in the delivery of health care in the nation, and initiated activities with such groups.

The NCHSR User Liaison Program conducted a one-day seminar on health care cost containment in general and prospective payment system in particular for various business and industry leaders from the State of Connecticut. This seminar was sponsored in cooperation with the Connecticut Business and Industry Association and North-Central Business Coalition on Health for the Greater Hartford area.

At the request of the Hawaii Business Health Council and the Hawaii Legislature, the NCHSR User Liaison Program sponsored a three and one half day workshop on hospital cost containment for senior legislative and executive branch officials and members of the Hawaii business community.

In 1984, the NCHSR User Liaison Program will be conducting a workshop on health care cost containment approaches for the Greater Portland (Oregon) Business Group on Health.

## USER LIAISON PROGRAM FUNDING

Question: Given the $1.6 million reduction in the amount the Administration proposes for NCHSR in FY 1985, can you assure me that there will be adequate funding to allow both a strengthening of the User Liaison Program's activities for state and local governments and a meaningful increase in activities carried out by this Program for business groups? More specifically, what is the magnitude of the funding that will be provided to these activities in FY 1985?

Answer: The budget for the State and Local Users Program in 1985 will be $600,000 including $260,000 for contract activities. Contract funds will be available for workshops, seminars, syntheses, and technical assistance to users, including business coalitions.

## TARGETED RESEARCH

Question: I understand that the bulk of the research funded by NCHSR is undertaken by grants. I'd appreciate it if you would explain to the Committee whether you feel steps should be taken to assure that a significant portion of the grants funded address issues of critical concern to leaders at the State and local level, and what steps you feel might be taken to involve State and local leaders in the development of research grants that will provide relevant and timely findings for such leaders.

The FY 1983 Committee Report called for, and here I quote, "the initiation in FY 1983 of at least two projects of directed contract research designed and monitored in close collaboration with State and local officials. Such projects should address current pressing health care delivery and financing issues and problems identified by State and local officials."

Would you please provide the Committee with a description of the two projects which were undertaken as a result of this Report language; an assessment of the value of the projects to the state and/or local governments involved; and the State and local officials who collaborated in these projects.

Also, would you describe similar projects that are underway or scheduled to commence in FY 1984?

Finally, would you provide the Committee with a statement describing existing plans to continue to undertake such directed contract research in FY 1985?

Answer: Research needs identified by State and local participants cover the broad range of research topics supported by NCHSR e.g., health promotion and disease prevention, long-term care, health care financing, insurance and regulation, and modeling for analytic tasks. Therefore, solicitations are not necessary to generate research proposals in these areas. Rather, NCHSR will continue to fund high quality research which is investigator-initiated through its extramural research grant program.

To date, no extramural targeted research questions have been identified by State and local users. However, State and local officials have worked with NCHSR's intramural staff to develop a project in long-term care. This project is exploring the feasibility of developing systematic models for forecasting future long-term care needs of a State's elderly population.

A representative from the User Liaison staff participates in all funding recommendations for extramural grant awards to assure responsiveness by NCHSR to State and local users needs. Also, a special mailing key for State and local users assures that NCHSR publications are disseminated to these officials.

## MEDICARE TRUST FUNDS

Question: In FY 84 Congress added money to your budget from the Medicare trust funds and provided report language describing our intent for the use of those funds. Please provide us with a detailed report on how those funds were used or are to be used.

Answer: In FY 1984 Congress authorized a transfer of $1,050,000 from the Medicare Trust Funds to support the analyses of medicare reimbursement issues, relevant research activities and dissemination of information to State and local governments.

- The funds are being used to respond to requests from HCFA pertaining to the safety and effectiveness of medical technologies and procedures that are being considered for coverage under Medicare.
- Extramural research grants will be funded.
- Through the User Liaison Program, the Center will also disseminate research findings to State and local governments, and conduct workshops for State and local health officials to advise them of research findings.

## BLOCK GRANTS

Question: For the third year in a row you are proposing legislation to move the Maternal and Child Health and Primary Care Block Grants to the Office of the Assistant Secretary for Health. You also propose --again--that the Family Planning, Black Lung and Migrant Health Programs be consolidated into the Primary Care Block as it is shifted to the Assistant Secretary. Congress in the past has given you no encouragement to believe you would get legislation allowing such a transfer and consolidation. What makes you think anything has changed at this time?

Answer: We have proposed this consolidation because it would provide a single point of contact for resolving management or administrative problems that occasionally arise and because it would make further Federal cost savings possible.

We believe that it is an appropriate time to transfer administration of the blocks since the transitional period for three of these grants is complete and they are fully operational. In addition, States have developed administrative systems for the operation of block grants and now require minimal Federal assistance.

Question: Congress has made it abundantly clear that it regards these block grants as vital health care programs that also give it a way to help the jobless who have lost their health insurance. Why do you persist in efforts to reduce federal administration of the blocks to the level of check-writing activity?

Answer: The underlying premise for the block grant concept is to permit States maximum flexibility in allocating resources for health care to meet the States' individual priorities. The consolidation will affect only administrative functions which are limited to reviewing grant applications, distributing funds according to formula, and reviewing State reports. It is important to note that technical assistance and health program consultation required by the States would still be provided by the appropriate PHS agency.

Question: How would the 15% set-aside projects under Maternal and Child Health be continued if, as you propose, the set-aside were eliminated?

Answer: The elimination of the Federal set-aside hinges on the strong feeling on the part of the Administration that States should have an increased level of decision making responsibility in regard to determining their own health needs and priorities. By its nature, a block grant program excludes the holding back of funds for various activities and the continuation of the set-aside is in conflict with this block grant philosophy. Under our proposal the entire MCH block grant appropriation would be allocated to the States. The States would have the option to support currently funded projects which they determine to be in accord with State needs and priorities.

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## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### GRACE COMMISSION REPORT

Question: Dr. Brandt, the Grace Commission report on the Public Health Service stated that in fiscal year 1982 there were approximately 184 unfilled positions in the Office of the Assistant Secretary for Health. If that statement is accurate it means that over 16 percent of your positions were unfilled. Why was this the case?

Answer: For Fiscal Year 1982, the position ceiling for the Office of the Assistant Secretary for Health was 1,526 and the actual on board as of September 30, 1982, was 1,439, for a total of 87 unfilled positions which is 6 percent of the total positions available.

Question: How many of your 1,066 positions are currently unfilled?

Answer: As of February 18, 1984, there are 61 unfilled positions or 6 percent of the authorized positions.

Question: How many of your 1985 permanent positions do you believe you will be able to fill?

Answer: It is anticipated that of the 1,030 positions requested in the 1985 budget an average of 1,010 or 98 percent will be filled throughout the year.

Question: Dr. Brandt, the Grace Commission report had some rather uncomplimentary things to say about the effectiveness of your office.

For example the report stated: "There is a general consensus among the staff support units at the agency level that the OASH personnel in the administrative staff units do little to assist them in fulfilling their mission".

The report goes on the say: "Several of the administrative staff units in OASH duplicate the functions in the agencies and the Office of the Secretary. The internal term used by PHS personnel for this duplication is 'shadow staff'".

How do you respond to these charges?

Answer: The administrative staffs at the agency level and at the PHS level perform similar but not duplicative functions. The offices at the agency level fully support the mission of that particular organization. The administrative staffs at the PHS level have a PHS-wide perspective and deal with policy matters as well as administrative issues.

The budget process is a good example of the kind of activity which is significantly different at the various organizational levels. Budget activities within one agency reflect that agency's priorities while the budget activities at the PHS level must incorporate the priorities of all PHS agencies. Another example is the grant policy area, where a PHS perspective is required to establish consistent research and research training grant policies for agencies with similar programs.

Question: The Grace Commission report recommended that your Office be dissolved and stated that overall staffing levels could be reduced by 448 positions as a result. Why shouldn't this recommendation be implemented?

Answer: The Grace Commission Task Force which examined the Public Health Service concluded that PHS is a group of independent agencies that have little need for coordination. While they concede that issues needing coordination occur "from time to time", they stated that these are relatively few considering the size of the Public Health Service.

Based primarily on this conclusion and the general consensus from a limited number of interviews at the agency level that administrative staff units do not help them fulfill their mission, the task force recommended the dissolution of OASH with the establishment of a senior line management level including an Assistant Secretary for Health. They noted that the Office of the Secretary should perform staff functions serving the line as necessary.

In our view, the basic Task Force premise that PHS is a group of individual agencies requiring little coordination is unfounded. In reality, the PHS agencies have many similarities of function which require significant programmatic and administrative direction.

For example, five separate organizational units within the Public Health Service perform research both extramurally and intramurally. Four of the health agencies support training of health professionals. One of our most promising areas of pursuit--disease prevention and health promotion--involves virtually every component of PHS. And three health agencies are providing technical assistance to states and territories receiving block grants.

The Assistant Secretary for Health must assure that the individual health programs--research, training, prevention, and block grants--are administered with consistent priority and a consistent focus to achieve a cohesive public health strategy. The success of the Federal effort to manage the health care system depends on the proper mix of these activities.

In order to carry out these responsibilities, the Assistant Secretary for Health must have a full staff complement to assist with policy development and implementation and administrative oversight.

In 1968, an organizational arrangement similar to the one now recommended by the task force was established and the Assistant Secretary for Health's role was primarily that of a staff advisor to the Secretary on health matters. In 1973, the PHS was reorganized to make the Assistant Secretary for Health the line manager of the PHS programs because the 1968 arrangement did not work. It had become apparent that agencies having such a diverse number of health programs could not be effectively managed by the Secretary without the existence of a strong Assistant Secretary for Health with full administrative support, exercising line management authority over these health programs. The arrangement established in 1973 has worked well and it has proven to be flexible enough to meet the changing requirements of the PHS over the past nine years.

## OASH EQUIPMENT

Question: Dr. Brandt, last year's appendix to the budget indicated that you expected to spend $589,000 on equipment in 1983. You actually spent $1,411,000. Will you explain those increased expenditures?

Answer: The increased expenditures primarily reflect the conversion of equipment from lease to purchase . For example, the National Center for Health Statistics purchased a major Computer Processing Unit. The 1983 payment for this unit including software was $501,000. The cost to rent this unit would have been $240,000 a year.

Fiscal Year 1983 was an opportune time to take advantage of advances being made in automated office equipment. The availability of word processing equipment has been a factor in enabling us to make reductions in the number of support positions required. These purchases were cost effective, providing savings for the government.

FAMILY PLANNING

Question: The regional allocations for family planning funds have been the subject of controversy for some time. The central issue appears to be the way in which each Region determines the number of clients served by Title X funds. It has been alleged that some Regions count patients served by all programs (Title V, Title XIX, Title XX in addition to Title X) whereas Region V has required its grantees to determine the number served only by Title X. Please clarify for the record the guidance the Department has provided to each regional office on this matter.

Answer: Title X clinics may be supported either wholly or partially by Title X funds. However in reporting the number of clients served all grantees have traditionally reported the total number of clients served by their clinics on the universal standardized system known as the Bureau's Common Reporting Requirements (BCRR). The instruction manual for the BCRR gives the following guidance in Section III (B):

> Organizations submitting the BCRR normally report on their entire activities even though they may be supported only in part by the BCHS grant(s); The scope of services or activities proposed in the approved application for BCHS grant funds will define the extent to which a grantee reports on the BCRR.

Question: What steps has the Department taken to assure that the Regional offices have complied with your guidance in this area?

Answer: Since the Department initiated the Bureau's Common Reporting Requirements (BCRR) in 1976, a variety of steps have been taken to assure that the Regional Offices complied. There is an instruction manual that details how to fill out the BCRR. Training sessions have been held to teach regional staff, service providers, and grantees how to correctly report their data. Clarifying memos have been issued. Most recently, the Office of Family Planning staff has met with Title X grantees in all ten Regions to discuss, among other things, compliance with the BCRR.

Question: Please provide for the record a listing of family planning clients served by all programs (including estimates for programs in which counts may not be required) for each Region with a second column listing the family planning funds allocated for each region in the last fiscal year.

Answer: The number of clients served and the Title X funds by region follows:

| Region | Clients* | FY 1984 Title X |
|---|---|---|
| I | 153,328 | $6,908,966 |
| II | 240,907 | 13,923,141 |
| III | 371,669 | 14,405,974 |
| IV | 847,314 | 29,457,213 |
| V | 383,516 | 19,351,387 |
| VI | 390,749 | 16,288,168 |
| VII | 162,218 | 6,920,329 |
| VIII | 86,500 | 4,216,106 |
| IX | 420,665 | 17,095,188 |
| X | 128,139 | 5,226,522 |
| TOTAL | 3,185,005 | $133,792,994 |

*Number of patients at or below 150% of poverty level who were served in calendar year 1982 by all Title X family planning programs.

Question: What is the current basis for allocating those funds to each region? What factors are considered in determining regional allocations?

Answer: The regional allocation of Title X service money is based on a three-part formula:

1. Twenty percent (20%) was prorated to the regions based on the number of women-in-need in each region. These are the number of women of childbearing age and at or below 150 percent of the poverty level, adjusted for those women not at risk of pregnancy (already pregnant, trying to be pregnant, etc.).

2. Thirty percent (30%) was prorated to the regions based on performance, the number of women below 150 percent of the poverty level actually served by the Title X grantees in each region compared to the national total.

3. Fifty percent (50%) was a funding stability allotment based on the amount each region received in prior years.

Each region also received $500,000 for national priority projects (e.g., natural family planning, infertility, family participation, and male involvement).

Question: There is considerable concern regarding the increasing percentage of funds that the Department has reserved for later allocation to "special projects". Provide for the record for the last five fiscal years the total funds reserved at the Departmental level for such projects as well as the percentage of the total appropriation these funds represent.

Answer: The allocations for national priority projects from FY 1980 to 1984 follow:

| Year | Dollars | % of Total Appropriation |
|---|---|---|
| FY 1980 | $7,150,000 | 4.41% |
| FY 1981 | $4,300,776 | 2.97% |
| FY 1982 | --- | --- |
| FY 1983 | --- | --- |
| FY 1984 | $5,000,000 | 3.6% |

Question: For the last fiscal year for which the information is available provide a listing of the projects funded by the Department under this discretionary authority.

Answer: A listing of the projects funded under this approach in past years was not maintained at the national level. We are asking the regional offices to provide us with whatever information they have and will provide their data as soon as possible.

## NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: Your budget justification indicates that the National Center for Health Services Research will be producing additional analysis of the data from the National Medical Care Expenditure Survey. This data is most helpful for evaluating many of the policy changes recommended by this Administration. Unfortunately that data was gathered in 1977. What steps is the Department taking to initiate a new survey so that we will have more current data for future policy decisions. When can the Committee expect a budget request for such a survey?

Answer: Recognizing the significant changes that are occurring and will continue to occur in health care delivery and financing and the need to provide reliable answers to current policy questions, the Department is committed to updating the data base of the National Health Care Expenditure Study (NHCES) supported by NCHSR. This study has provided information on costs and use of health care, the breadth and depth of health insurance coverages, sources of payment for major components of care using a 1977 data base. Estimates and analyses from the data base have been furnished to the Congress and Executive Branch employer-provided health benefits, health care coverage for the unemployed, and Medicare cost-sharing.

The critical need for current data can be met by updating NHCES and we are developing plans for this activity.

## SMOKING AND HEALTH

Question: You are requesting $3,535,000 in fiscal year 1985 for smoking and health, an increase of $3,000 above the current budget.

I notice that the National Heart, Lung and Blood Institute spends a substantial amount of money on programs that are intended to motivate people to stop smoking. For example, over $160,000 is being spent to establish the feasibility of developing, implementing and evaluating a self-help smoking cessation program for employees of the University of Alabama in Birmingham.

Can you tell us how your smoking program interacts with the Institute with regard to these grants?

Answer: The Institute interacts with the Office of Smoking and Health (OSH) in three ways. First, the Institute uses the publications of OSH to keep up with the state of the science and to develop initiatives for research programs. The annual Surgeon General's report is used as a definitive document on smoking research; the Bibliography on Smoking and Health is also a useful document for the community conducting smoking research. Second, the Institute is working closely with OSH to provide a recommended outline and potential authors for the 1984 Surgeon General's Report on Smoking and Chronic Obstructive Pulmonary Disease. Third, the Institute participates with OSH in the Interagency Technical Committee on Smoking and Health, in which representatives of several Federal agencies share information on current and planned programs on smoking and health. In this forum, research findings and planned programs are presented and discussed. Group comments are often incorporated into our programs. The Institute will continue to maintain a close working relationship with that office in order to avoid unnecessary duplication and enhance cooperation.

Question: As you say in your justification the Smoking and Health Program serves as the focal point for all Departmental Smoking and Health activities. How much will the National Heart, Lung, and Blood Institute spend on programs that motivate people to stop smoking in FY 1985 and what will the Department spend in this area in total in the coming year?

Answer: In 1985 the National Heart, Lung, and Blood Institute will spend $7.5 million on smoking and health activities. In total, the Department will be spending approximately $36.3 million in 1985 to combat smoking and understand its destructive effects on health as indicated on the following table:

Public Health Service
Smoking and Health Activities
(dollars in $000)

| | 1983 | 1984 | 1985 Request |
|---|---|---|---|
| NIH | | | |
| Cancer | $9,262 | $15,000 | $18,248 |
| Heart, Lung, and Blood | 6,553 | 7,300 | 7,500 |
| Environmental Health | 1,218 | 1,205 | 1,200 |
| Child Health | 2,224 | 2,400 | 2,400 |
| Research Resources | 443 | 491 | 494 |
| NIH, Subtotal | 19,700 | 26,396 | 29,842 |
| ADAMHA | | | |
| Drug Abuse | 1,442 | 2,200 | 2,600 |
| OASH | | | |
| Smoking and Health | 2,141 | 3,535 | 3,538 |
| CDC | | | |
| Chronic & Environmental Health | 340 | 357 | 357 |
| PHS Total | $23,623 | $32,488 | $36,337 |

## OASH - NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: Dr. Brandt, on page two of your opening statement you referred to the work of the National Center for Health Services Research (NCHSR) in these words:

> "NCHSR funds provided for the original work on Diagnosis Related Groups (DRG's), that is, the development and testing of homogeneous patient classes from the perspective of resource consumption."

On the other hand, the justifications for the Health Care Financing Administration had this to say in describing their request for $35 million in research, demonstration and evaluation funds:

> "Research activities developed the per case payment methodology for the prospect payment system based on a diagnosis related groups (DRGs) approach."

Can you tell us who did what in the area of DRG research?

Answer: NCHSR funded a major research project by Yale University in 1969 to examine alternative methods of measuring outputs at hospitals. This research, conducted between 1969 and 1976, examined case mix and alternative funding mechanisms and established the base for the concept of DRGs. The group concept and the technology that was necessary to look at variations in resource consumption were established through this early research.

HCFA conducted the early tests and demonstrations to determine the feasibility of applying the DRG concept to hospitals and developed the system and data base needed to implement the Medicare prospective payment nationwide. At the request of the Congress, HCFA is now looking at the impact of Prospective Payment on hospitals and at ways to extend the DRG concept to other segments of the health care system. Current activities are devoted to demonstrations to test proposed changes in reimbursement mechanisms, changes in coverage eligibility, and new management approaches.

Question: You indicate in your opening statement that the Center's work "will be essential in assessing the impact of the DRG prospective payment system." HCFA in their justifications make reference to the Center but characterize its work as having a "secondary application" to HCFA programs. Do you agree?

Answer: The Center conducts research on the health care system generally; particularly on the structure, organization, and behavior of health resources. Since the change to Prospective Payment of hospital services under Medicare will inevitably affect all aspects of health care, the Center will study the overall impact and, in particular, the impact on the demand for, and supply of, health resources and the implications of Prospective Payment for projecting future resource needs, both public and private. Not only is it important that HCFA be aware of the direct effects of prospective payment on the Medicare system, which it studies, but it must be aware of these "secondary" effects as well.

Question: You are requesting $17,286,000 for health services research. The Health Care Financing Administration plans to spend $35 million on research, demonstration and evaluation next year. Please tell us where your responsibilities end and HCFA's begin.

Answer: The National Center is the principal support for basic research studies of a general nature on the delivery, financing, and administration of health care services. The Center seeks to develop a better understanding of the processes by which health care services are made available and how they may be provided more efficiently, more effectively, and at a lower cost. An important focus of this research is the development of new ideas for structural reform in the health care system, including alternative health care delivery methods and cost-saving measures within hospitals. Other research looks at services delivery for the disadvantaged, changes in health manpower needs, and issues regarding the quality of care. As examples, NCHSR recently completed a study on the effect of reduced Medicare payment rates on physician practices and a study on the relation between home health and nursing admissions. Many projects done by the Center also demonstrate how improvements in health service delivery can reduce the cost of care (i.e., unnecessary x-rays, more effective cardiac units, generic drug substitution). In addition, NCHSR is responsible for technology assessment activities in the Department and in assisting HCFA in making decisions on Medicare coverage issues. Examples of technology assessments include: renal dialysis for schizophrenia, heart pacemakers, and home blood glucose monitors for diabetics.

HCFA, in contrast, conducts applied research studies oriented toward improving the efficiency of Medicare and Medicaid expenditures. HCFA research is highly program relevant and focused on management, regulatory, and legislative improvements in the two programs it administers. The bulk of current research is looking at the impact of the recently enacted Prospective Payment system on hospitals and at ways to extend the system to other segments of the health care system. More specifically, HCFA is, for example, examining ways of incorporating capital and outpatient services in the prospective payment system and alternative methods of reimbursing physicians under Medicare. In the past, HCFA's research efforts have led to program reforms which resulted in significant savings to Medicare and Medicaid, such as elimination of the routine nursing salary differential and reductions in malpractice payments.

We fully recognize the interrelationship between the research programs of the agencies, and to avoid duplication of research efforts we have encouraged coordination and cooperation at the planning and project development stages. Duplication is avoided through required exchange of annual plans and through plan review and oversight by the Office of the Secretary.

Question: Do you have a mechanism in place to insure that you are not duplicating research being supported through HCFA? If so, describe it.

Answer: There are three mechanisms for avoiding duplication. First, in the Spring of each year, every research program in the Department reviews its research strategy and prepares a revised plan. These plans identify changes in research emphasis and direction, and describe major initiatives. Plans are exchanged among appropriate agencies and are reviewed by the Office of the Secretary in conjunction with the development of the budget request. Second, project staff are encouraged to consult broadly in the development of a new project. Such consultation not only involves staff from the two research programs but from the operating programs and outside researchers as well. Finally, systems have been established to exchange information on grant applications, and personnel from the Center often sit on HCFA project review panels.

## SUBCOMMITTEE RECESS

Senator **WEICKER**. The subcommittee will stand in recess until tomorrow when we will meet at 9 a.m. in room SD–116, Dirksen, to hear witnesses from the Health Care Financing Administration, the Social Security Administration, and the Office of Refugee Resettlement.

[Whereupon at 10:45 a.m., Tuesday, March 27, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, March 28.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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**WEDNESDAY, MARCH 28, 1984**

U.S. Senate,
Subcommittee of the Committee on Appropriations,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Mark Andrews presiding.

Present: Senators Weicker, Andrews, Proxmire, and Burdick.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**STATEMENT OF DR. CAROLYNE K. DAVIS, ADMINISTRATOR**

**ACCOMPANIED BY:**

**JOHN MAHONEY, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT SERVICES**
**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS**
**JAMES SCOTT, ACTING DEPUTY ADMINISTRATOR, HCFA**

### PREPARED STATEMENT

Senator Andrews [presiding]. The hearing will come to order.

Today we will hear from the Health Care Financing Administration, which has responsibility for administering the medicare and medicaid programs. Because of its specific responsibilities, the agency has been described as resembling a giant health insurance firm. It has more than 4,000 employees and proposes a budget of more than $98 billion in fiscal 1985.

A major portion of that budget consists of the medicare trust fund, which is not the specific responsibility of this subcommittee. The portion that does fall under this subcommittee's jurisdiction totals about $42 billion and involves the Medicaid Program and a number of medicare activities that are handled through direct appropriations or trust fund transfers.

Here to tell us about the agency's budget is Dr. Carolyne Davis, Administrator of the Health Care Financing Administration.

Let me say that I personally appreciate your cooperation over the past weeks. I know the subcommittee appreciates the job you are doing.

We would like to have you introduce your colleagues and proceed with your opening statement.

[The statement follows:]

## STATEMENT OF DR. CAROLYNE K. DAVIS

It is my pleasure to be with you today to present the FY 1985 Budget for the Health Care Financing Administration. Before I go over the highlights of our appropriations request, I wish to point out that our FY 1985 Budget plays a crucial role in serving the 50 million elderly, poor and disabled who depend on Medicare and Medicaid to meet their health care needs.

We are ever mindful of the need for striking the proper balance between our humanitarian concerns and fiduciary obligations as trustees of public funds. We have worked closely with the Congress on this issue, and the Congress has responded by legislating sweeping reforms over the last few years, such as the Omnibus Reconciliation Acts, the Tax Equity and Fiscal Responsibility Act (TEFRA) and the Social Security Amendments of 1983. The most notable of these was the enactment last year of prospective payment for hospitals, which we all agree is landmark health legislation.

We have begun to reap the benefits of those changes. For example, largely as a result of the Reconciliation Acts of 1980 and 1981, the rate of increase in Medicaid expenditures has declined considerably over recent years. Between FY 1981-1985, Medicaid outlays under current law are increasing at an average annual rate of approximately 10 percent--a significant decrease from the annual rate of 15 percent experienced from FY 1975-1980. As a result of the reforms in TEFRA and the Social Security Amendments of 1983, we have also been able to reduce the annual rate of increase for Medicare Hospital Insurance Benefits from 20.6 percent from FY 1975-1980 to the current rate of 13.4 percent.

These changes represent a significant improvement in health spending policy. Health care costs, however, continue to grow at unacceptably high rates, resulting in bipartisan awareness of the need for spending discipline in those programs.

Few human needs in life are so universally basic and crucial as access to health care. And few issues are at once so delicate and so pressing for a nation as ensuring the continued affordability of such care for its citizens. Over the past few years, our prospects have brightened. However, there remains much work to be done.

For that reason, our FY 1985 budget proposes to build on our recent accomplishments and reintroduces reform measures which have not yet been enacted. Key Medicare measures in our FY 1985 plan propose to freeze physician reimbursement for one year; begin Medicare eligibility on the first day of the month following attainment of age 65; and establish a voluntary voucher program to permit Medicare beneficiaries to select private health plans more suitable to their particular needs. The proposal to change the tax treatment of costly employer-provided health benefits, in order to stimulate consumer awareness and help reduce total health care costs, will also increase revenues to the Medicare Hospital Insurance Trust Fund. Although these legislative proposals are not within the purview of this Committee, we hope that you will nonetheless lend your personal support to the enactment of these measures.

I would now like to proceed with a brief overview of our appropriations request.

### Grants to States for Medicaid

The Medicaid program provides grant funding to 54 States and territories for medical care for 23 million low income persons. Our FY 1985 request for Medicaid of $21.2 billion includes the Administration's legislative proposals.

The legislative initiatives proposed for the Medicaid program are:

- Maintain Omnibus Budget Reconciliation Act (OBRA) reductions in Federal payments at a rate of 3 percent (estimated Federal savings of $567 million);

- Require nominal cost sharing by Medicaid recipients (estimated Federal savings of $270 million); and

- Assign Third Party Liability rights to Medicaid (estimated Federal savings of $7 million in 1985).

In addition, several changes proposed for the Aid to Families with Dependent Children program result in estimated Federal savings of $230 million to Medicaid and the net impact of the Medicare proposals would result in a cost of $7 million to Medicaid.

A number of improvements have been made in the Medicaid program in the last 3 years. With the added flexibility provisions of OBRA, States are now able to use innovative and cost-effective approaches to provide health care to needy people. For example, under the home and community-based services waiver program, Medicaid may now pay, at no additional cost, for certain services which help recipients receive community-based care as an alternative to costly institutionalization.

In addition, the Administration has sought to improve the effectiveness of Medicaid through such efforts as enhancing States' Third Party Liability (TPL) operations and the strengthening of the Early and Periodic Screening, Diagnosis and Treatment program which serves about 2 million children each year.

## Payments to Health Care Trust Funds

Our FY 1985 request for this account is $19.9 billion -- an increase of $2.2 billion or 12.6 percent. It is comprised of the following elements:

- Federal payment for Supplementary Medical Insurance -- $19.0 billion;
- Hospital Insurance for the Uninsured -- $762.0 million;
- Military Service Credits -- $84.0 million; and
- Hospital Insurance for Uninsured Federal Annuitants -- $38.0 million.

## Program Management

This account provides funding for a variety of Medicare and Medicaid program-related management activities. The total FY 1985 request of $ 1.2 billion, of which $96 million is appropriated from general funds and $1.1 billion is authorized to be transferred from the Medicare trust funds, covers the following program activities:

### 1. Research

Results gained from research, demonstration and evaluation projects contribute to major program changes. Prior year investments in this area have produced information critical to the development of legislation and program changes in areas such as prospective payment system development, HMOs and temporary extension of the Medicare program to cover hospice benefits.

We are requesting $35 million for research in FY 1985.

We are also requesting a $4 million supplemental appropriation for FY 1984 to support prospective payment related studies mandated by the Congress. The supplemental will enable HCFA to undertake six of the prospective payment studies mandated by Congress in the Social Security Amendments of 1983. These studies relate to: development of an equitable payment methodology for sole community providers; development of a system to make hospital price comparison data available to patients; development of a prospective payment methodology for currently exempted hospitals; examination of the impact of alternative State systems of hospital payment; the appropriate treatment of uncompensated care costs; and, coordination of selective information transfer between Parts A and B of Medicare.

In addition to the continuation of prospective payment studies and refinements, the FY 1985 budget reflects research priorities in the areas of physician payment reforms; increased competition through alternative Medicare and Medicaid financing approaches; and, the development of prospective payment methodologies for nursing homes and home health agencies.

## 2. Medicare Contractors

This budget activity provides funding for operating costs incurred by fiscal agents, primarily insurance companies, in administering the Medicare program. Key functions for which Medicare contractors are responsible are claims payment and provider audits and medical reviews.

The FY 1985 budget reflects a continuation of our increased emphasis on audit and medical review activities. The Administration believes that this initiative is even more critical and cost beneficial in view of the need to ensure the successful implementation of the new prospective payment system. The budget also reflects strengthening of third party liability efforts by contractors to ensure appropriate payment by third parties where Medicare is the secondary payor. Funding is also requested for several other management improvements.

We are requesting $918 million for this budget activity in FY 1985. This amount represents approximately 1 percent of Medicare benefits paid by contractors. We are also submitting legislative proposals which would improve our ability to manage the Contractors and would save, in FY 1985, $10 million.

## 3. State Certification (Medicare)

The State Certification program is responsible for ensuring that both institutional and non-institutional providers rendering health care services to Medicare patients meet acceptable quality and safety standards. Annual agreements are negotiated with State agencies to perform surveys of health care facilities in accordance with explicit criteria.

The FY 1985 request for Medicare certification activities and program support services is $50 million. This is in addition to the resources required for Medicaid survey and certification which are included in the Grants to States for Medicaid appropriation request. Our FY 1985 request provides for overall survey coverage of approximately 67 percent of the providers participating in Medicare. Within that total level of funding, we will continue to survey 100 percent of long term care facilities and hospices. The budget will fully meet our obligation for ensuring the protection of beneficiary health and safety.

## 4. ESRD Network Coordinating Councils

End-stage renal disease (ESRD) network coordinating councils are responsible for reviewing quality of care and efficient utilization of resources devoted to kidney dialysis and transplantation services. However, we believe that the role the Councils perform can be adequately assumed within other HCFA programs, and we will again be submitting a legislative proposal to terminate the Councils. Our request is on a current law basis which includes $4.5 million for FY 1985.

## 5. Administrative Costs

Administrative costs support HCFA staff and operating expenses required to manage the Medicare and Medicaid programs. Major ongoing functions are the articulation of policy, regulations, and guidelines regarding program coverage, beneficiary eligibility, reimburse-ment and conditions of participation; the negotiation of agreements with fiscal agents and grantees; and the monitoring and evaluation of contractor, grantee, and health care provider performance.

Our request for FY 1985 is $219 million, which essentially maintains FY 1984 staffing and funding levels. The Full Time Equivalent (FTE) level of 4,033 represents a reduction of 17 percent from our 1981 budget. Through reorganization, the agency has been able to meet its commitments at the same time as we have absorbed an overall decrease in personnel. I would like to stress that, although this budget reflects the phase out of our direct claims payment services to Medicare providers, we are taking steps to ensure a smooth transition for affected providers and employees. Our commitment is that no HCFA employee will be separated or adversely affected as a result of this change. Rather, the employees involved will be transferred to other positions within HCFA to aid in the implementation and monitoring of prospective payment and other legislation, as well as in strengthened efforts in fraud, waste and abuse elimination and in data collection and review.

## 6. Prospective Payment Assessment Commission

The budget also requests $1.5 million for the Commission, which was created by the Social
Security Amendments of 1983 and which advises the Secretary and the Congress on prospective payment-related issues.

That concludes my prepared remarks, Mr. Chairman. I will be happy to answer any questions the Subcommittee may have.

### Grants to State. ; Medicaid

(Dollars in Thousands)

| ACCOUNT | 1983 ACTUAL | 1984 REQUEST | 1984 APPROPRIATION | 1984 REVISED REQUEST (Including Supps. & Rescis.) | 1985 ESTIMATE (for each activity) |
|---|---|---|---|---|---|
| Grants to States for Medicaid: | 19,398,191 | 20,772,449 | 20,673,708 | 20,708,579 | 21,222,000 |
| Vendor Payments: | 18,383,640 | 19,554,709 | 19,588,027 | 19,658,676 | 20,015,126 |
| State and Local Administration: | 1,014,551 | 1,217,740 | 1,085,681 | 1,049,903 | 1,206,874 |
| 1st Quarter Advance | (5,115,600) | (5,561,000) | (5,552,000) | (5,561,000) | (5,980,000) |

## Payments to the He[illegible]are Trust Funds

(Dollars in Thousands)

| ACCOUNT | 1983 ACTUAL | 1984 REQUEST | 1984 APPROPRIATION | 1984 REVISED REQUEST (Including Supps. & Rescis.) | 1985 ESTIMATE (for each activity) |
|---|---|---|---|---|---|
| Payments to the Health Care Trust Funds: | 15,347,000 | 17,682,000 | 17,682,000 | 17,682,000 | 19,904,000 |
| Supplementary Medical Insurance: | 14,238,000 | 16,811,000 | 16,811,000 | 16,811,000 | 19,020,000 |
| Military Service Credits: | 207,000 | 79,000 | 79,000 | 79,000 | 84,000 |
| Hospital Insurance for Uninsured: | 877,000 | 750,000 | 750,000 | 750,000 | 762,000 |
| Federal Uninsured Payment: | 25,000 | 42,000 | 42,000 | 42,000 | 38,000 |

## Program Management
(Dollars in Thousands)

| ACCOUNT | 1983 ACTUAL | 1984 REQUEST | 1984 APPROPRIATION | 1984 REVISED REQUEST (Including Supps. & Rescis.) | 1985 ESTIMATE (or each activity) |
|---|---|---|---|---|---|
| Program Management: | | | | | |
| PSRO | 15,000 | 0 | 13,000 | 13,000 | 0 |
| T/F Transfer | -15,000 | 0 | -13,000 | -13,000 | 0 |
| B.A. | 0 | 0 | 0 | 0 | 0 |
| Research | 30,300 | 30,000 | 31,000 | 35,000 | 35,000 |
| T/F Transfer | -10,000 | -12,000 | -10,400 | -14,400 | -12,000 |
| B.A. | -20,300 | 18,000 | 20,600 | 20,600 | 23,000 |
| Medicare Contractors | 820,000 | 837,000 | 862,000 | 862,000 | 917,600 |
| T/F Transfer | -820,000 | -837,000 | -862,000 | -862,000 | -917,600 |
| B.A. | 0 | 0 | 0 | 0 | 0 |
| State Certification | 32,835 | 37,532 | 39,600 | 39,600 | 49,759 |
| T/F Transfer | -32,300 | -36,932 | -39,000 | -39,000 | -47,074 |
| B.A. | 535 | 600 | 600 | 600 | 2,685 |
| ESRD | 4,546 | 4,546 | 4,837 | 4,837 | 4,546 |
| T/F Transfer | -4,546 | -4,546 | -4,837 | -4,837 | -4,546 |
| B.A. | 0 | 0 | 0 | 0 | 0 |
| Administrative Costs | 193,926 | 201,051 | 209,000 | 209,000 | 218,830 |
| T/F Transfer | -122,842 | -136,613 | -140,000 | -140,000 | -148,268 |
| B.A. | 71,084 | 64,438 | 69,000 | 69,000 | 70,562 |
| Positions | 4,382 | 4,217 | 4,216 | 4,216 | 4,216 |
| Prospective Payment Commission | 0 | 0 | 0 | 1,500 | 1,500 |
| T/F Transfer | 0 | 0 | 0 | -1,500 | -1,500 |
| B.A. | 0 | 0 | 0 | 0 | 0 |
| Total Program Management | 1,096,607 | 1,110,129 | 1,159,437 | 1,164,937 | 1,227,235 |
| T/F Transfers | -1,004,688 | -1,027,091 | -1,069,237 | -1,074,737 | -1,130,988 |
| B.A. | 91,919 | 83,038 | 90,200 | 90,200 | 96,247 |

## INTRODUCTION OF ASSOCIATES

Dr. DAVIS. Thank you very much, Mr. Chairman.

On my left is Mr. Jack Mahoney, who is the Director of the Office of Financial Management Services of HCFA, and on my immediate right is Jim Scott, who is the Acting Deputy Administrator of the Health Care Financing Administration. To his right is Mr. Anthony Itteilag, who is the Deputy Assistant Secretary for Budget in the Department.

With your permission, I would like to proceed by highlighting my statement.

Senator ANDREWS. You certainly may, and let me assure you your statement will appear in the record as though given in its entirety.

Dr. DAVIS. I will be very brief then.

## BUDGET HIGHLIGHTS

We tried to construct our budget this year with a proper balance between our humanitarian concerns and our fiduciary obligations, and clearly this is a balance that in recent years Congress has worked very closely with us to achieve.

We looked back over the recent efforts and progress in health care cost containment. We know Congress has legislated sweeping reforms over the last several years in the Omnibus Reconciliation Act, the Tax Equity and Fiscal Responsibility Act, and the Social Security Amendments of 1983.

We suspect the most notable of all of these enactments was prospective payment for hospitals which clearly was landmark health legislation. I think we have begun to reap the benefits of many of these legislative reforms.

For example, the rate of increase in medicaid expenditures has declined considerably over recent years. Between 1981 and 1985, medicaid outlays are increasing at an average annual rate of approximately 10 percent, a significant decrease from the annual rate of 15 percent experienced from fiscal year 1975 to 1980.

We have also been able to reduce the annual rate of increase for the medicare hospital insurance benefits from approximately 20 percent between 1975 and 1980 to the current rate of 13.5 percent.

These kinds of legislative reforms represent a very significant improvement in health spending policy. But it is obvious that we need additional spending discipline in order to safeguard the future of medicare and medicaid benefits.

Our fiscal year 1985 budget has some proposals that build on our recent accomplishments. We've reintroduced some reform measures that have not yet been enacted.

Our key medicare measures are: to freeze physician reimbursements for 1 year while we study the entire area of physician reimbursement reforms; to begin medicare eligibility on the first day of the month following attainment of age 65; and, to establish a voluntary voucher program to give medicare beneficiaries the option to select a private health plan that may be more suitable to their particular needs.

In addition, a proposal to change the tax treatment of costly employer-provided health benefits will also have a beneficial effect on medicare.

Now, if I can proceed to an overview of our appropriations request.

### MEDICAID APPROPRIATION

For grants to States for medicaid, our fiscal year 1985 request is $21.2 billion, and assumes enactment of the administration's legislative proposals. These include: maintaining the Omnibus Budget Reconciliation Act reduction in Federal payments, but at a rate of 3 percent; instituting nominal cost sharing for medicaid recipients; and, assigning third party liability rights to medicaid.

A number of improvements have been made in the Medicaid Program in the last 3 years, primarily by improved State flexibility and also the use of the waiver programs, especially home- and community-based service programs.

We find that State medicaid programs have been very interested in this, and a number of the States have requested waivers in this area that will help the recipients receive community-based care as an alternative to more costly institutionalization in nursing homes.

In addition, we have sought to improve the effectiveness of the existing programs through enhancement of States' third party liability operations and through strengthening the treatment of the estimated 2 million children that are involved in the Early Periodic Screening, Diagnosis and Treatment Program.

### PAYMENTS TO MEDICARE TRUST FUNDS

In relation to payments to the health care trust fund, our fiscal year 1985 request is for $19.9 billion, and that covers the following activities: Federal payment for supplementary medical insurance which is the largest component and is $19 billion; hospital insurance for the uninsured is $762 million; military service credits is $84 million; and hospital insurance for uninsured Federal annuitants is $38 million.

### PROGRAM MANAGEMENT

Program management provides funding for a variety of program-related management activities, and the total request is for $1.2 billion, which covers the following activities:

### RESEARCH

First of all, we are requesting $35 million for research. Our 1985 research agenda will reflect priorities in the area of physician payment reform, increased competition through alternative financing proposals in medicare and medicaid, and development of prospective payment methodologies for nursing homes and home health agencies.

We are also requesting a $4 million supplemental to our 1984 appropriations in order to support the prospective payment-related studies that were mandated by the Social Security Amendments of 1983. The results of most of these studies are due to Congress by April 1, 1985.

We find our present fiscal year 1984 appropriation level of $31 million is insufficient to begin all of these studies. Of the 18 that were mandated, we have been able to initiate all but about 6, and we are requesting a supplemental of $4 million in order to initiate the following 6 studies:

One, the development of an equitable payment methodology for sole community providers; two, development of a system to make hospital price comparison data available to patients—those that are financed both by public and private programs; three, a development of prospective payment methodology for the current exempt hospitals; four, examination of the impact of alternative State systems of hospital payments; five, the treatment of uncompensated care costs and appropriate adjustments to large treatment hospitals, especially in rural areas; and six, coordination of the information transfer between part A and B of medicare.

## MEDICARE CONTRACTORS

In relation to our medicare contracting budget, we are requesting $918 million for fiscal year 1985. This reflects the continuation of our increased emphasis on audit and medical review activities. We believe that this initiative is critical and cost beneficial in view of the need to successfully implement prospective payments.

We are also planning on strengthening third party liability efforts where medicare is a secondary payer.

## STATE CERTIFICATION

Our fiscal year 1985 budget contains a request for medicare survey and certification services of $50 million in addition to our medicaid survey and certification activities that are included in the grants to States for medicaid account.

Our fiscal year 1985 request will provide for an overall survey coverage of approximately 67 percent of all of our medicare providers. However, we will be surveying 100 percent of the long-term care facilities and 100 percent of the hospices.

The budget will fully meet our obligations, we believe, for ensuring the protection of our beneficiaries' health and safety.

## END-STAGE RENAL DISEASE NETWORK

We will again be submitting a legislative proposal to terminate the End-Stage Renal Disease Network Coordinating Councils. Pending termination through congressional action, there is a request for $4.5 million in the fiscal year 1985 budget.

## FEDERAL ADMINISTRATION

We have a request for $219 million for administrative costs for fiscal year 1985. That will essentially maintain our fiscal year 1984 staffing level. We have a full-time equivalent level of 4,033, and that represents approximately a 17-percent reduction from our fiscal year 1981 budget.

Through reorganization the agency has been able to meet its commitments and has become increasingly productive, as Congress has given us a number of new areas to move to strengthen our activities. Implementing prospective payment, for example, attests to this fact.

Although the budget reflects the phaseout of our direct claims payment services to medicare providers, we are taking steps to ensure a smooth transition for both the affected providers and the employees. Our commitment is that no HCFA employee will be separated or adversely affected as a result of this change. Rather, we will reassign the employees within HCFA in order to aid ongoing priorities, such as, the implementation and the monitoring of prospective payment legislation and to strengthen our efforts in eliminating fraud, waste, and abuse and to improve our data collection and review activities.

Those are essentially the highlights of my remarks, Mr. Chairman. I would be happy to answer your questions.

Senator ANDREWS. Thank you, Dr. Davis.

Let me get into a couple of questions from my own back yard, so I can tell you how things are going, better than any other way.

## HOSPITALS IN MINOT, ND

A month ago today, as you remember, you met with the North Dakota congressional delegation in my office regarding the urban classification of Minot, ND, under the new medicare reimbursement regulation. Can you share with us at this time any progress that's been made regarding this issue and what kind of determination you come up with?

Dr. DAVIS. Yes, sir; as you recall, in our conversation, I indicated there were two things we need to address. One was the restructuring of the area wage index. We have had some indications that the area wage index did not appropriately differentiate between part-time and full-time employees. We have sent out a questionnaire to each hospital in order to obtain an accurate count for their full-time and part-time workers. It is our intent, once we get that data, to integrate it into a revised area wage index calculation that will be in effect beginning October of this year.

An additional problem deals with the identification of a regional referral center. I have called a meeting of a number of the hospital associations for this Friday to help us to identify the proper criteria for a regional referral center. We intend to try to achieve some degree of consensus.

Senator ANDREWS. Do you feel, Doctor, then, that that is still a possibility?

Dr. DAVIS. Oh, yes.

Senator ANDREWS. And that eventually you will be able to correct the inequity that this hospital and others like it, I'm sure, in other parts of the country fell into that was inadvertent. I don't think it represented the congressional intent, nor, as I understand it, does it represent the intent of you and your Department.

Dr. DAVIS. I think that there are different problems in different areas of the country, but as I understand the problem of the Minot Hospital, it's clear that their issue falls in the area of the regional referral center definition. It appears they have some of those characteristics. And we do know we want to fix that. There are some additional issues, such as boundary lines, some of which can be addressed in October and some of which are part of the phasein to a totally national system. Some may be a part of our study for Congress on the whole issue of urban/rural designation and whether we should have them. That study is more comprehensive and, of necessity, will take a little longer.

Senator ANDREWS. But in the case of Minot Hospital, as you know so well, even though they do treat more medicare patients than a hospital in another town in North Dakota, that one designated as urban and Minot designated rural, there's a 20-percent pay differential which would bankrupt the hospital in very short order.

Finally, we appreciate the fact you're making this progress, and I'm sure you will notify our office as to the results of that progress.

### DIFFICULTY OF RETROACTIVE ADJUSTMENTS

Finally, when this fear is resolved, one of the two hospitals in Minot, of course, does not come under the new regulations until July 1. But the other hospital, St. Joseph's Hospital, has been operating under the new regulations since January 1. If Minot is exempted—and it seems that it will—will it be retroactive for the sake of St. Joseph's Hospital?

Dr. DAVIS. Senator Andrews, it would be very difficult for us to retroactively adjust these rates, because we are under a congressional mandate for budget neutrality, which had to be calculated before we moved into this.

Second, I point out the regional prospective payment portion is only 25 percent of the hospital's total rate this year. So the likelihood of this having a significant impact is fairly diminished, I believe.

Senator ANDREWS. Nonetheless, it will have an impact. It's significant in their mind. It may not be significant in your mind, in your dealing with the megabucks, but because of this question of retroactivity, I assume that you will move as rapidly as you can to implement your decision.

Dr. DAVIS. Absolutely.

Senator ANDREWS. When can we expect a decision, Doctor?

Dr. DAVIS. Well, we expect it to be ready at the beginning of the second year under the system. The proposed regulations will be published on June 1, and like anything else, we will allow for a 60-day comment period and then come out with the final regulations on September 1, to be implemented in year two, starting in October 1, 1984. We would make those determinations, based upon input that we will be getting.

As I indicated earlier, we will be having discussions that I hope will arrive at a consensus about the regional referral center definition. But obviously, a few organizations can't represent the entire spectrum, so we will need to gather additional comments before we implement it in the second year.

Senator ANDREWS. So you will implement it when?

Dr. DAVIS. Starting with fiscal year 1985, which would be October 1.

Senator ANDREWS. In other words, St. Joseph's Hospital has to let the clock run until that date? There is no way that could be corrected?

Dr. DAVIS. Because of the issue of budget neutrality, there is no other way. We have already determined the rates and allocated funds for this year, based upon assumptions we had at that point in time.

### IMPACT ON NONPROFIT HOSPITALS

Senator ANDREWS. How does a nonprofit hospital like St. Joseph's, that will lose $650,000 because of this kind of determination, how does it recover that $650,000?

Dr. DAVIS. I would be surprised if, indeed, the figure is of that magnitude since what we are discussing impacts upon only 25 percent of their payment. It may well be that that's the total amount that would be lost once the full system was implemented.

Senator ANDREWS. St. Joseph's Hospital calculated it would be $650,000. And you have a hospital in a town that's been remodeling, trying to give the best service it can to patients in a 200-mile radius, because it is a regional hospital. You saddle it with $650,000 in losses, because you don't come up with a decision early on, and the question has to be whether they recover. They can't get $650,000 from private patients. Can they sock it to the patients that come in under Blue Cross? Blue Cross doesn't have the resources to recover that. What do they do?

Dr. DAVIS. Well, I'd be happy to look at their cost data. I know they have already shared that with us, and we are studying it.

Senator ANDREWS. That's why it's so appalling to us, the time lag. One, you have agreed just a moment ago that this is inadvertent, this was not deliberate on your part, and two, we have established that it will be a devastating cost to a nonprofit hospital. And three, they don't have any idea where they can pick up $650,000, and you don't have any idea.

What happens?

Dr. DAVIS. Well, I asked my staff to analyze the data to determine whether it's an actual loss or if it's a loss against what the revenues would have been under an urban designation. Those are two different points. We have talked with some hospitals, and I'm not saying Minot is one of them, where they have indicated the reason they are going to lose money is that they are losing money against what their revenue would have been, if they had been determined to be urban. But my problem, Senator Andrews, is that we are mandated to budget neutrality. The only way I could do anything about this would be to go back and take money away from everybody else, because the distribution of the money has been calculated for this first year.

Senator ANDREWS. I don't think anybody calculated money to the point of trying to, in effect, shut a hospital or a set of hospitals in an area that desperately needs that medical care. And these are hospitals that have been remodeling to meet the needs of the future there, because the smaller-town hospitals have turned largely into being long-term patient care rather than acute patient care hospitals, referring patients into the Minot Hospital. There's got to be some way of addressing it, rather than just hanging a sign on the door and, in effect, say, the Reagan administration forces this hospital into bankruptcy.

Dr. DAVIS. Senator, it's clearly not our plan to do that. We'll see what we can come up with, but I can't promise action before October 1984, because of the issue of budget neutrality. We're certainly willing to study and see.

Senator ANDREWS. Well, there's got to be some recommendation that you can come up with in a case as absurd as this, so that we can write something into the appropriations bill, we can do something along the lines to make this retroactive.

I don't think that the chairman of this subcommittee, and the Senator from Wisconsin, wherever they happen to be, want to have this kind of thing happen, because we're merrily going along the slow, methodical process in Government needed to work it out. Meanwhile, a nonprofit institution out there falls further and further behind.

### CARES PROGRAM

I have one final question, and I know my colleague from North Dakota, Senator Burdick, has a couple of questions that will follow up my questioning, on another hospital incident out there.

Yesterday, in the subcommittee hearing, I talked with the people about the CARES project from HRSA. CARES is an outpatient rehabilitation program, which allows the physically disabled to receive quality care while living 400 miles or so away from a rehabilitation facility. It's been saluted as being totally cost effective. It brings the top-flight doctors in rehabilitation out to the smaller communities, where they work with the patients, and the family practice doctors, instead of moving the patients in, and it's a good program.

Now we were informed yesterday that CARES will receive continued Federal funding for fiscal 1985, yet in your job you have come up with a new definition of a medical director of a rehabilitation hospital, and your definition states the medical director can only serve inpatients.

Now if you keep that definition, you kill off this program, because the idea is to take the medical directors out for 2 to 3 days in this small town in the western part of the State, 400 miles away, where it does, in fact, extend into a rural atmosphere, this is a kind of health care delivery service that can't be given any other way, except at much higher cost.

Have you found a way—and we mentioned this a month ago, too—have you found a way to resolve this glitch in the regulations, which I think was inadvertent?

Dr. DAVIS. It clearly was not addressed by the regulations. Our attempt was, not pay for a director who was inappropriately spending part of his time in other types of service delivery outside of the rehabilitation unit.

Senator ANDREWS. Well, if that's the language, Doctor, and since there isn't any other type of delivery service outside the area, this particular instance would clearly be exempt.

Dr. DAVIS. Well, as always, when we try to be specific, we sometimes find ourselves caught in some traps of our own making. But if we're not specific, it's difficult for our intermediaries to interpret exactly, with consistency, what we did intend in regard to activities which count toward meeting the full-time requirements for directors of rehabilitation units. Activities which should be included are administrative duties; supervision of services furnishing direct care to inpatients, evaluating the suitability of potential inpatients prior to admission, reviewing the plans of treatment for the inpatient, and participating in multidisciplinary conferences.

It strikes me that this is an area, where we have to study a bit more to determine whether or not it is feasible to not penalize this type of program, but yet not pay for inappropriate activities outside the rehabilitation area.

## CARES PROGRAM IN NORTH DAKOTA

Senator ANDREWS. That's true, but in this case, the medical director—the rehabilitation hospital is a State-owned facility. It's part of the University of North Dakota. The patients to be admitted to the rehabilitation hospital are North Dakotans and the rehabilitation hospital happens to be located in the extreme eastern part of the State. The medical director, in going to the west under the CARES Program is, in effect, working with patients who, under the rules, would be eligible for treatment in the hospital. He's not working with a different class of patients at all.

Dr. DAVIS. Yes; I understand that.

Senator ANDREWS. And if he doesn't extend him with two or three of his doctors to Williston and to Dickinson, then all of those patients will have to come into Grand Forks at considerably greater expense. So he's not getting out into a satellite area of responsibility. He's doing his specific duties, given the basic charge that's given that hospital.

Dr. DAVIS. Senator Andrews, I will be happy to look into this and get back to you in the next couple of weeks with some possible answers.

Senator ANDREWS. Do you think an exemption in this case could well be in order?

Dr. DAVIS. I would like to reserve the right to study this particular issue, because it had not come to my attention yet.

Senator ANDREWS. We mentioned it a month ago, Doctor.

Dr. DAVIS. I have not had an opportunity to really study this particular area.

Senator Andrews. But here again, we get into a time-sensitive situation. Senator Weicker and I are planning to go out to see the Williston operation. A number of television news services are going to carry a story about the anniversary of this unique service extension. It works. It saves money. It saves $4 for every dollar we invest in the program. It's been an ongoing program since 1979, and we would think it would be of sufficient importance, so you could give us a favorable ruling that would allow it to continue rather than to be confounded by a regulation that just happened to come out of your establishment.

Dr. Davis. It does sound like a unique situation, and I would like the opportunity to get back to you within the next month.

Senator Andrews. Do you need any further information?

Dr. Davis. I'll have to check with my people and find out.

Senator Andrews. Our people can give you good information. Senator Burdick, I know you have questions on either this or on the New Rockford issue, which I didn't cover.

Senator Burdick joins me in what I have said on Minot and I'm sure on the CARES project as well as the New Rockford one which I support him on.

### TRINITY HOSPITAL

Senator Burdick. You're correct, Mr. Chairman. I just have one question about Trinity Hospital before we go to New Rockford.

What is going to be the situation about the Trinity Hospital if no accommodation can be reached before the fiscal year 1985? Is there any retroactivity or anything else that can be accomplished?

Dr. Davis. Senator, I'm not familiar with this particular issue. It has not been brought to my attention, I'd be happy to study it.

Again, in relation to retroactivity, the system as designed by Congress is to be budget neutral, and we have allocated all of the funds in developing the rates for this fiscal year. The issue of budget neutrality, I think, is a significant concern to us and there would be no way for us to retroactively make adjustments. There is no money left to adjust with unless we take money away from all the other hospitals. I think that would severely jeopardize an important feature of the prospective payment system in terms of allowing hospitals to plan.

But I will be happy to get back to you on the specifics of this particular hospital. Trinity Hospital in New Rockford?

Senator Burdick. Oh, no. We're still talking about Minot.

Dr. Davis. Oh. I'm sorry. I thought I heard something about New Rockford.

Senator Burdick. We'll talk about New Rockford, too.

Dr. Davis. I'm familiar with Minot. I'm not familiar with the other one.

Senator Burdick. Would your answer be any different than you gave Senator Andrews?

Dr. Davis. Well, I do try to be consistent. There is a problem with retroactivity because of budget neutrality, Senator.

## SOLE COMMUNITY PROVIDERS

Senator **Burdick**. All right. Now, getting to New Rockford, the city hospital there has applied for status as a sole provider. It is only 16 miles from the nearest like hospital, but the people in their service area utilize city hospital almost exclusively.

We are working with your Denver regional office on this and they have been very cooperative, but the problem is your regulation which states that the nearest, closest hospital must be "* * * inaccessible for at least 1 month out of each year" in order for a hospital to qualify as a sole provider.

There are a lot of stories about how cold it is up in our area, but we're not that inaccessible. According to AAA, there are only nine highways in the entire Nation, outside of the State or national parks, which are closed for a month or longer because of the weather.

This makes your criteria extremely narrow. There are other situations in which the weather is a critical factor.

For instance, in the area around New Rockford there was a wind chill of at least minus 20 degrees on 50 percent of the days between last December and February. On one-third of those days there were travel advisories due to severe weather conditions.

While this bad weather alone may not qualify as a sole community provider, I am concerned that your criteria, based only on the weather, does not allow consideration of an accumulation of factors. For instance, the county around New Rockford has the highest population of elderly in the entire State. Twenty-seven percent of the people are over 60 and 20½ percent are over 65.

For these frail older people bitter cold and icy winds every 2 or 3 days effectively has made their local hospital the sole community provider, even if the road to another hospital is officially open.

## EXEMPTION TO SOLE COMMUNITY PROVIDER CRITERIA

In looking over your regulations, I do not see any consideration allowed for those few counties where the elderly population is so high that prolonged weather conditions would play a significant factor, even if the road isn't closed for a month at a time.

Would you take into consideration those particular factors?

Dr. **Davis**. I'm going to ask Mr. Scott, who has been in the operations area, to address that issue, Senator.

Mr. **Scott**. Senator, when we developed the criteria for sole community provider we tried to find the appropriate balance between recognizing the very real need for access to health care in rural communities and the recognition that we needed to have in place the appropriate kinds of incentives for efficient management. That balancing act became very difficult as you clearly articulated.

The function of the sole community provider exemption is to allow some relief in those places where, if a given hospital is not paid enough money and goes out of business, there would be no health care in that area.

As we have looked at that over the years—and we have been involved in this under a different program for quite a few years—we have tried to measure basic access to care and something that would reflect the ability of people to get to needed health care services.

Mileage is, as you know, one of the basic criteria. The issue of inaccessibility of roads is an argument that has come, of course, many times from the folks in the more mountainous States.

We struggled with that at different times. People argued for 50 miles, 20 miles, 25 miles. The numbers that we came up with were the numbers that we thought struck that reasonable kind of a balance.

I think you raise some very good issues. We, like in the case of regional referral centers, are new in this game, Senator, and very clearly that's the kind of input we need.

We have been asked by Congress to develop a long-term study on the issue of sole community providers. So we're clearly not in a position to say "We know all the answers." We have put some criteria out that we thought were very reasonable.

What I would like to do is to take a little bit of our time at Dr. Davis, and my level, and look at this with the Denver regional office to see if the additional criteria you have talked about might fit and what kind of sense they really make.

Senator BURDICK. I appreciate that very much. Here you have a county that's remote and rural, and 25 percent of the inhabitants are elderly people. So that's a factor that should count as much as closing the roads.

Mr. SCOTT. I think that's the kind of thing that deserves more of our time to look at it; and I think we should do that.

Senator BURDICK. Could you give me a time schedule when you're going to look at it?

Mr. SCOTT. Very soon. [Laughter.]

Senator BURDICK. Well, I think the next question isn't necessary in view of what you said and I thank you.

Mr. SCOTT. I can guarantee the answer will be correct. [Laughter.]

Senator BURDICK. It's on the record.

Mr. SCOTT. One reason I'm sensitive, Senator, is that I come from western Kansas where we also have many counties that have a high percentage of rural people and small hospitals.

Senator BURDICK. We got you on our side. [Laughter.]

### PROSPECTIVE PAYMENT

Senator WEICKER [presiding]. Last year the Federal Government implemented a major change in the way hospitals are reimbursed under medicare known as prospective payment. Would you please tell us about the program and to what extent it has been implemented, and is it a success?

Dr. DAVIS. We began to phase the program in according to the hospital's fiscal year starting October 1, 1983. We now have approximately 42 percent of all hospitals, or roughly 2,782, that are being paid under prospective payment and the bulk of the hospitals will be coming on line when their fiscal year begins.

The next major group will come on line in July and by the end of the fiscal year 1984 we will have all 5,357 acute care hospitals on the prospective payment system. There are some exempt areas because the model under which we devised the system was based upon data from the acute care hospitals.

I believe that prospective payment has resulted in some significant changes in administrative practice within the hospitals and we're beginning to see some significant changes in practice patterns. I think that's an important long-range goal that we were intending to accomplish.

We are keeping track of what is happening on a monthly basis and expect to issue yearly reports back to Congress on the implementation and the success. I think we have found a few very minor glitches, some of which we have been talking about, such as boundary lines, regional referral centers with urban/rural designation.

But on the whole the system has begun to demonstrate that it does work. I would point out that the system is for payment of inpatient care only, and that there are still major slices of revenue that go to the hospitals that are not included within this system. Not included are capital-related costs, direct and indirect medical education costs, bad debts, and, of course, there are additional payments for outliers.

Although these are outside of the payment rates that are promulgated, I would say on the whole the system is evidencing success.

### URBAN/RURAL RATES

Senator WEICKER. How are you handling the so-called rural hospitals which actually may be adjacent to high cost metropolitan areas but only get the rural rate?

Dr. DAVIS. That is a particular problem that we have been studying, Mr. Chairman, and I think it breaks down into two aspects. The first is the area wage index. The area wage index was something that was used in the past, but there wasn't necessity for it to be finely tuned. As a result, little attention was paid to the fact that it was based on data which did not differentiate between full-time and part-time workers nor between salary and overtime. But now hospitals have quickly pointed out to us that since labor costs account for 80 percent of the rate and since that is the part that is now indexed by the area wage index, it is important to have it as accurate as possible.

We have worked with the hospital industry and have developed a questionnaire which we are using, to solicit additional input so that we can correct the wage area index. We have a revised version ready for year two. In addition, we are trying to study the issue of what is an appropriate regional referral center and I have indicated that we will have a meeting with the hospital industry this Friday to try to address more specific criteria that can be utilized in the identification of the regional referral center.

Finally, in examining the impact of our rates on hospitals I think one has to be careful about whether or not hospitals are subject to an actual loss of revenue because they are adjacent to but not in an urban area, or whether it is simply that if they had been designated as urban they would be paid a higher amount. Obviously they would desire to get the higher rate since it is somewhere between $50 and $300 higher depending upon the location in the country.

I would finally point out that the urban/rural designation was not something the Department had initially recommended. It was something that Congress defined and mandated as part of an implementation strategy.

We do have a report due back to Congress by the end of fiscal year 1985 that has to deal with the whole issue of whether we should continue to have the rural/urban designation.

Senator ANDREWS. Mr. Chairman. Doctor, when you say that Congress gave you this directive to define rural and urban, that's true. But did Congress tell you that the rural hospital had to arbitrarily be set at 20 percent below the urban hospital even though it has essentially the same cost factor?

It was to determine different cost factors, as I understood the legislation that came from Congress. You're the ones that set up the fact that a so-called rural hospital 100 miles away from an urban hospital would get 80 percent of the payment that the urban hospital got.

Dr. DAVIS. Senator, as it happens when you designate a particular geographic area, you must collect costs data from each hospital within that area and average it together, and that determines your rate for that specific urban/metropolitan zone. In addition, then you take all of the hospitals that are collectively in the rural area and take the average of all of their costs, and that gives you your rural rate.

Senator ANDREWS. I know that.

Dr. DAVIS. So when the calculations are done that's the difference that's indicated.

Senator ANDREWS. What we're pointing out, as we have been pointing out, is that we have a hospital that has actually more patients than a hospital that's classified urban and whose costs, because of the labor index, are precisely the same as the urban hospital. Nonetheless it's arbitrarily set at 80 percent of the charge basis.

That differentiation of 80 percent of what it takes to keep them whole was done by your regulations and not by the legislation.

Dr. DAVIS. It is correct that the system of averaging works within both the urban and the rural. That is the intent of the system.

### REGULATORY INTERPRETATION OF STATUTE

Senator ANDREWS. But the point is Congress didn't say to you to take the Minot hospitals of this country and arbitrarily tell them they could only charge 80 percent of what their competing hospitals that had the same cost basis were charging.

That came out as a result of the way you interpreted the statute.

Dr. DAVIS. Well, I think that there is clearly only one way to interpret the statute. If you have a group of hospitals designated as urban and others designated as rural because of the geographic locations, the methodology is such that you have to take the average cost for each one of those hospitals within that geographic area.

Senator ANDREWS. Well, the reason for the question is not to be arbitrary with you in any manner, shape or form. The reason for my question is to develop that if the costs for this hospital that we determined earlier will lose $650,000 over a 9-month period—if the cost for that freakish distortion in what charge they can have came about because of regulation, then it can be corrected through regulation change and it doesn't have to be corrected through legislative action.

I would assume, since it came about because of the way the regulations were drawn, it can be corrected by regulations. Is that not true?

Dr. DAVIS. One can look at a different method of defining those hospitals that are clearly on that borderline. I will point out, Senator, that I have not met any hospital administrator that believes they should be defined as serving a rural area.

It's most interesting that any hospital administrator that I have talked with believes that they compete in the urban area in relationship to their wages and their other costs. Yet for a long time now, we have had a designation of urban and rural.

Senator ANDREWS. The thing is that this particular hospital—and I dwell on it as an example of what is wrong—sits adjacent to one of the largest airbases in this country, an airbase that doesn't have a hospital. So this pair of hospitals in Minot, ND, is providing service for Air Force critical patients in a B–52 bomber wing in a base that encompasses 150 minuteman missiles, in a base that has 12,000 Air Force personnel; and, arbitrarily, somehow or another, out of the clear blue sky came the designation from your shop that this hospital complex in Minot is a little rural unit.

You know, it takes patients in from 100 miles away and, as we pointed out in the meeting a month ago, it has a greater patient load than a similar hospital designated as urban. Yet you say they should only charge 80 percent of the fees the other hospitals do even though they have the same pay schedule and they have a bill before the subcommittee that Senator Weicker and I sit on, the Defense Subcommittee, wanting to spend $30 million to build a base hospital at the Air Force base.

That's the type of medical care that the U.S. Government says needs to be in this community. These hospitals are providing that care, and the authorizing committee struck that hospital from their request saying that they could get the care they needed from these hospitals that you classify as rural.

That's why I say something happened on the way to the classification that we hope can be corrected.

Dr. DAVIS. Well, Senator, as I indicated to you, I believe, in our meeting, the issue should be: Who should be classified as a regional referral center and how do we get that particular designation more clearly defined.

The revised criteria for a referral center, I believe, will resolve the particular problem in not only Minot, but in a number of other situations.

Senator ANDREWS. And there are a number of other situations equally egregious.

Dr. DAVIS. We have heard from them.

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Thank you, Mr. Chairman.

First, Dr. Davis, I haven't heard you testify before. I am deeply impressed. You stood up to some difficult questions. You have handled the questions, I think, extraordinarily well with great poise and under difficult circumstances.

There are no two Senators from any State that are more persistent in fighting for their State than the Senators from North Dakota.

Dr. DAVIS. Yes; I agree with you on that.

Senator PROXMIRE. I think you have been very courteous and very firm in your responses. [Laughter.]

Senator ANDREWS. Let me assure the Senator that something is going to be delivered or we will write it in the darn bill. [Laughter.]

Senator PROXMIRE. You received some pretty good promises.

Dr. Davis, if you will forgive me for discussing a national—— [Laughter.]

### DECREASE IN MEDICARE/MEDICAID COST GROWTH

In your opening statement you refer to significant reductions in the rate of increase in medicare and medicaid costs between the years 1975 to 1980 and the years 1980 to 1985.

Isn't that decrease in the rate of increase attributable primarily to a reduction in the rate of inflation between the late seventies and the early eighties, rather than changes in the law and changes in the administration of the program?

Dr. DAVIS. Well, let me divide these two and discuss both medicaid and medicare.

I think the reduction in the area of medicaid is clearly a result of both the reduction in the rate of inflation but additionally to more prudent management that has resulted from the incentives under the OBRA.

Senator PROXMIRE. Do the constant dollar statistics show a significant decrease in medicare and medicaid cost growth?

Dr. DAVIS. I believe we will have to submit that for the record.

[The information follows:]

RATE OF INCREASE IN CONSTANT DOLLARS

| | Fiscal year— | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 | 1984 | 1985 |
| Medicaid | 6.2 | 3.3 | 1.9 | 2.8 | 5.9 | 7.6 | −5.5 | −2.1 | 0.8 | 2.8 |
| Medicare: | | | | | | | | | | |
| Part A | 8.5 | 8.7 | 8.2 | 4.8 | 7.5 | 8.6 | 7.8 | 5.9 | 7.9 | 7.1 |
| Part B | 12.6 | 9.6 | 7.7 | 10.5 | 10.9 | 10.3 | 7.2 | 7.6 | 9.8 | 10.0 |

## MEDICAID RATE OF GROWTH

Dr. DAVIS. For the last 3 years the rate of growth in medicaid has been less than the rate of growth of national health expenditures.

Senator PROXMIRE. Well, for the record could you just break it down and show how much of the reduction in the rate of increase is the result of——

Dr. DAVIS. I think, very clearly, the States have moved to aggressively manage their programs much more than they have in the past and have taken a great deal of interest in both the freedom of choice and the home- and community-based services waivers. Since 50 percent of the medicaid budget is spent on nursing home care initiatives in the area of home- and community-based services will have a very significant impact on decreasing outlays.

## PHYSICIAN REIMBURSEMENT

Senator PROXMIRE. Increases in physician reimbursement under medicare have been particularly difficult to control. Between 1975 and 1980 they rose by 154 percent. In 1982 they increased 21 percent. The estimated increase for 1983 is 19 percent—a total of 40 percent over just 2 years.

Your Inspector General has suggested that the Government could save $154 million over a 5-year period by adopting the multiple visit concept now applied to intermediate care facility physician visits to skilled nursing facility visits.

Are you seriously considering that recommendation?

Dr. DAVIS. We are studying the issue of physician reimbursement in general, Senator. That is one of a number of issues that we are looking at in relation to physician reimbursement.

Clearly, Congress has mandated that we study the whole area of physician reimbursement. They indicated that we expand our research efforts to examine the advisability and feasibility of restructuring the physician reimbursement system and integrating the rate for physician payments, for inpatient acute care, into the DRG payment system.

Again, I would stress both its advisability and feasibility. We have several research studies examining these issues, but in the interim, we are recommending a 1-year freeze on the indexing of physician fees.

Senator PROXMIRE. But if you adopt the multiple visit concept, that wouldn't require any legislation, as I understand it. Is that right?

Dr. DAVIS. It is my interpretation that it wouldn't.

Senator PROXMIRE. It would not?

Dr. DAVIS. I don't believe it would.

Mr. SCOTT. Senator Proxmire?

Senator PROXMIRE. Mr. Scott.

Mr. SCOTT. If I could add something to that.

In the area of physician reimbursement, in addition to the legislative changes that we have proposed, we are working very closely with our carriers who administer the program to identify approximately 15 to 18 medical review screens, which we would put in place before bills are to be paid.

These are screens that would examine the frequency of visits and would try to raise a flag if something does not look like it is appropriate. These claims would be pulled out of the claims processing procedure for some type of medical review I believe that the multiple visit concept is one of the issues Dr. Davis is considering in the screens.

We are looking for ways that can identify patterns of practice that we may be able to influence, but as I mentioned before with Senator Burdick, you need to be balanced. We don't want to interfere unnecessarily.

Senator PROXMIRE. When do you think you can make a decision on that approach?

Mr. SCOTT. We will have those by October 1.

### EXPERIMENTAL MEDICAL TECHNOLOGIES

Senator PROXMIRE. Dr. Davis, on March 15 Congressman Pepper held a hearing on the cost of unproven medical technologies. At that hearing the editor of the New England Journal of Medicine claimed that $5 to $10 billion a year is being wasted on useless or dangerous medical technologies. Following the hearing, Chairman Pepper said that careful screening of new technologies—and refusal to pay for unneeded methods—could in time save $50 billion a year, enough to prevent the financially threatened Medicare Program from having to cut benefits.

Can you tell us what steps, if any, you are taking in this area, especially relating to payments made for physicians' services?

I realize that the prospective payment system should take care of part of the problem.

Dr. DAVIS. The issue of coverage of new technology is an area where we do take our responsibility very seriously. In fact, many criticize us for being rather slow in our process.

But before we determine that new treatment modality is nonexperimental, we make a rather extensive review, not just in the Health Care Financing Administration with our physicians advisory group, but if they deem there should be further input from physicians we turn to the Assistant Secretary for Health in the Public Health Service and ask them to look at the issues.

If they think that there is sufficient merit for widespread input, they will request that. In addition, they might, as they have in several instances, ask for a consensus conference.

Senator PROXMIRE. Could the editor of the New England Journal of Medicine and Chairman Pepper, both of whom are recognized as real experts in the field, possibly be close to the target when they say you could save $50 billion a year eventually?

This is an awesome amount.

Dr. DAVIS. Well, I am not an authority in judging the potential savings. It is evident that we wouldn't want to pay for inappropriate treatment. That is one of the reasons why the Medicare Program is particularly conscious in making decisions and, as I have indicated, is sometimes criticized for being slow in making a determination in the appropriate use of new technology. I would rather be criticized for being slow and being more sure of the decisions that are being made, sir.

### MEDICARE LABORATORY SERVICES

Senator PROXMIRE. An Inspector General's review of medicare laboratory services has indicated that, first, medicare payments for lab tests are much higher than prices independent laboratories charge physicians; second, kickbacks are being made to providers for referral of medicare laboratory work; third, physicians claim that they perform laboratory tests when, in fact, the tests are done in outside laboratories; and, finally, carriers are paying for individual tests that should have been reimbursed as part of a panel of tests at lower rates.

I understand that a draft task force report on medicare reimbursement policies recommended that medicare pay for laboratory services on the basis of a national fee schedule.

Where does that recommendation stand?

Dr. DAVIS. That draft task force report has been submitted, and we are gathering input from people in the Department. I expect that sometime in the next couple of months we will reach some agreement on that particular proposal.

Senator PROXMIRE. Will you reach an agreement by the end of May?

Dr. DAVIS. They tell me it is on my schedule for next week.

Senator PROXMIRE. Oh, great. Thank you.

### PACEMAKER MONITORING UNDER MEDICARE

Dr. Davis, the Department's Inspector General sent you a memorandum on November 3 of last year indicating you could save $194 million over the next 5 years by reducing the frequency of pacemaker monitoring allowed by medicare and by reducing individual monitoring payments to the lowest charge level.

The report pointed out that the monthly standard was set back in 1980 before improved technology, including more reliable batteries, was available. In fact, some doctors feel it is a psychological burden for an elderly medicare patient to be told that the pacemaker has such a high risk of malfunction that it must be monitored monthly by telephone.

Have you implemented these recommendations, and, if not, why not?

Dr. DAVIS. We have implemented some of the ideas in relationship to coverage guidelines. We have been working very closely with the Public Health Service because they have the knowledge about the technology, and they helped us very much in developing coverage guidelines to indicate when it was appropriate in terms of medical necessity.

Right now we are working on new guidelines that would indicate the medical necessity for the more sophisticated types of pacemakers. These indicate when one would do post-implant monitoring and those we anticipate should be out in the near future.

### RETURN ON EQUITY

Senator PROXMIRE. Late last year, the Department's Inspector General was critical of HCFA for paying profits to proprietary home health agencies. The IG said that these payments were illegal and indicated you could save $3.5 million a year if you stopped paying profits.

An article in the New York Times covering this issue pointed out that last April the Congress reduced the profits paid to hospitals for inpatient services by one-third but that the Department contends it can still pay the higher rate for hospital outpatient services, skilled nursing homes, home health agencies, and other facilities that seek to make a profit.

Even if we assume that the law allows you to make these payments, why should you continue to do so if you can cut the deficit by reducing or eliminating profit payments?

Dr. DAVIS. Our general counsel reviewed this and concluded that it was valid and supported by statutory authority to recognize a return on equity payment to all of the proprietary providers.

We are studying that whole issue of return on equity as a part of our capital study that is due in October of this year to Congress, and we will certainly address that issue as a part of the overall study on capital.

### PHYSICIAN REIMBURSEMENT

Senator PROXMIRE. Finally, I would like to ask you a question about Dr. Albert Sabin's suggestions for reducing medical care costs. This year the administration is requesting $19 billion for payments to physicians under medicare. Dr. Albert Sabin who, as you know, was the developer of polio vaccine, has recommended that the Government reduce medicare costs by requiring that medicare physicians be salaried and not be allowed to charge patients on a fee-for-service basis.

What is your reaction to this proposal?

Dr. DAVIS. Well, we are ourselves embarked on examining the whole issue of physician reimbursement, but at this point in time I would certainly not want to see us take that particular suggestion.

I think that payment to physicians merits a great deal of study. We would want to assure ourselves that there is still availability and access to treatment, services for the beneficiaries, and that is why we have embarked upon a several-pronged effort.

I spoke earlier about the research efforts, and in addition, I have an informal advisory group of physicians who are working with me on a monthly basis to examine a variety of issues that impact on physician reimbursement. I would like to await the outcome of a number of these efforts before I would make any recommendations as to the appropriate methodology for physician reimbursement.

But we oppose making a sudden, swift move to salaries because I don't think we have the ability to implement it safely right now.

### HIGH TECHNOLOGY DIAGNOSTIC PROCEDURES

Senator PROXMIRE. Dr. Sabin also said that too many high technology diagnostic procedures are carried out because they are reimbursable.

Do you agree, and if so, what is HCFA doing to come to grips with this problem?

Dr. DAVIS. Well, there is no doubt that our regional and national trend data indicate there are different rates of hospitalization experienced for, say, hysterectomies or tonsillectomies or some of the more elective types of surgery. We are looking at this particular area.

Senator PROXMIRE. I am talking about diagnostic procedures.

Dr. DAVIS. I am talking about the kinds of diagnostic procedures for which we have some data, and one of the things that we have been trying to do is to share that data widely.

Clearly, in the medical review process these are the kinds of activities that are being examined. In addition, we encourage a voluntary second opinion program, and these two are the kinds of activities that need to continue to be encouraged to the point that the beneficiary making the decision himself would have an additional input from, say, a second source.

Mr. SCOTT. Senator, in addition, those procedures that would be performed on an inpatient basis are now no longer paid on a cost basis. They are on a fee-for-service basis instead, and are included in the fixed DRG payment.

To the extent that there are things being done that are not necessary or not going to be particularly useful for the patient, then there is a very strong incentive, with a fixed payment for the inpatient cost, for the hospital and the medical staff to take a long hard look at those and reduce them.

### MEDICARE HOSPITAL REIMBURSEMENT

Senator PROXMIRE. Dr. Sabin has recommended that medicare hospital reimbursement be limited to nonprofit institutions.

Why wouldn't this be a good idea?

Dr. DAVIS. Well, it seems to me we now have both for-profit and nonprofit hospitals in this country, and to limit the payments to all the not-for-profit might indeed mean that some parts of the country would not have access to needed care services. I believe something like 10 or 11 percent of all the hospitals in the country are for profit. They have been able to demonstrate that they can deliver adequate quality care.

Senator PROXMIRE. Have you made any kind of a survey to determine how the elimination of that 10 or 11 percent of for-profit hospitals would affect the availability of hospital care for medicare patients?

Dr. DAVIS. No, sir, I have not. This is the first time I have really heard about Dr. Sabin's recommendations. So it has not come to my attention before.

Mr. SCOTT. It would vary tremendously, Senator, from State to State. There are some States and many communities where that would have a very serious effect.

Senator PROXMIRE. That is what I would be concerned about. I wouldn't expect you to make a study that would cost a substantial amount, but it seems to me it might be useful to make at least a superficial survey to determine if limiting medicare reimbursements to nonprofit institutions would be cost effective.

I have great respect for Dr. Sabin, and I know you do, too. If his suggestions could produce savings it would be helpful.

Thank you very much.

Thank you, Mr. Chairman.

## PROFESSIONAL REVIEW ORGANIZATIONS

Senator WEICKER. Thank you, Senator Proxmire.

There will be other questions from myself and other members of the committee for response to the record, but one that I would like to conclude with here is: For fiscal 1984, we have provided you with $13 million for utilization review, with the understanding that this would be all that is necessary to make the transition from Professional Standards Review Organization to the new Professional Review Organization. We are, therefore, somewhat surprised to learn you fall short of funds to keep the PSRO's afloat until the transition is completed next October 1.

We have heard the shortage may be as much as $4 to $5 million.

Now what seems to be the problem? Is it a matter of a delay in getting the regulations out? Maybe you'd like to use this occasion to clarify that?

Dr. DAVIS. I have not heard that we need additional funds. Although the PSRO budget is quite tight, and it does not allow for movement away from a very rigid timetable to implement the Peer Review Organization. We did publish regulations on February 27, that designate the areas and followed that the next day with a request for proposal [RFP] to the 47 different areas of the country where the prospective payment system has been initiated. We expect to have those proposals back into the Health Care Financing Administration by April 27, and would anticipate that by the end of July we will implement the first peer review organizations. This means that by October 1, we will need to have implemented all of the peer review organizations nationwide. This is a very tentative schedule, but I believe if we are very careful and we don't have any unforeseen delays, we will be able to reach our goal, and have the entire PRO Program implemented by October 1, in which case, we would not need any additional funding.

If something totally unexpected happens, and we can't meet our schedule, I would first look at spending patterns in our other program management accounts to see if there are any potential funds that could be reprogrammed into this area. However, I believe if we can adhere to our schedule, which is a bit tight, and we are committed to implement that schedule, we should not be in need of any additional funds for the PSRO Program.

Mr. SCOTT. Mr. Chairman, our goal is for a smooth transition from the current medical review programs to the new Peer Review Organization. The worst of all possible worlds would be for the existing functions to stop for a period of time before we can implement the PRO Program. The medical review activity is our primary line of defense for payment safeguards under the new Prospective Payment Program.

So as Dr. Davis has indicated, if something happens and it looks like we might have difficulty in maintaining the full medical review activities, we will be contacting you.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. All right. That's all I've got in the way of questions.

Thank you very much.

As I said earlier, there will be some additional questions to be answered for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

## MEDICARE

Question: We are all concerned about the possible insolvency of the Medicare Trust Fund. Thus, I noted with interest, the projection in your budget that this "insolvency will not occur during the current five-year budget period (1985-1989), given current economic assumptions."

To what extent is this true -- and how does the projection compare with what the Board of Trustees of the Medicare Trust Fund will state in its report to the Congress which is due April 1? (A separate group, the Advisory Council on Social Security, recently stated that Medicare outlays would exceed income "before the end of the 1980's.")

Answer: It is true that under budget assumptions, the Hospital Insurance Trust Fund will remain solvent through the projection period (FY 1985-FY 1989). The 1984 Trustees Report will show that under both sets of intermediate assumptions, the Trust Fund will be depleted during 1991.

Question: Is there any truth to the rumor that the Trustees will project bankruptcy of the Medicare Trust Fund by 1991?

Answer: That is correct in regard to the Hospital Insurance Trust Fund. The Supplementary Medical Insurance (SMI) Trust Fund, which is financed on a year-to-year basis, does not have the same problem.

Question: What economic assumptions, such as growth in real wages which directly affects Trust Fund income, led to the budget's projection that insolvency will not occur in the 1985-1989 period? What do you think the trustees will assume on this same score?

Answer: The budget assumptions reflect steady progress in sustaining economic growth and in reducing inflation including hospital inflation, interest rates, and unemployment. The 1984 Trustees Report gives the status of the Trust Fund under four different sets of economic assumptions ranging from optimistic to pessimistic. With the exception of the most pessimistic assumptions, we doubt that bankruptcy will be projected within the 1985-1989 period.

Question: Supplementary Medical Insurance -- Part B of Medicare -- provides coverage for doctor bill and outpatient services to Medicare beneficiaries. We note that you are requesting a $2.2 billion increase in this appropriation for fiscal year 1985. Why the big jump?

Answer: The increase for the last two years is not out of line with historic growth of this appropriation. Most of that growth is due to the largest activity, the Federal Payment for Supplementary Medical Insurance. This activity, along with enrollee premiums, finances the benefits provided under the Part B program. Thus, the increase in this appropriation is a function of the continued growth in the Part B benefit outlays. The average annual increase for Part B benefits from FY 1979 to FY 1983 was 20.6%, the increases for FY 1984 and FY 1985 are projected to be 16.3% and 16.5%, respectively. If the President's legislative proposals are enacted, the FY 1985 increase can be reduced by 36%.

Question: I notice the Part B premium increased on January 1 from $12.20 per month to $14.60 per month. This is designed to help put the public's contribution around 25 percent of Part B costs. What would happen if the public's share were raised to 35 percent as some have proposed? Would many of the elderly have difficulty paying that monthly premium?

Answer: Our budget and legislative proposals in FY 1984 and FY 1985 recommend that the Part B premium be raised to 35 percent of program costs. We have reviewed the impact of this premium level on the elderly, and we find that the impact on the average beneficiary would be slight. The increase would be spread over all 29 million Part B enrollees. Several important features are incorporated in our proposal to assure that a premium increase would not impose a financial hardship on those least able to pay. These features are a phase-in of the premium increase over several years and a hold harmless provision that would protect current Social Security income. We estimate that fewer than 50,000 beneficiaries would need protection from a hold harmless provision. Such a premium increase would bring the beneficiary contribution more in line with the original design of the program which required beneficiaries to pay for 50 percent of program costs.

Question: You have requested $38 million to reimburse the Medicare Trust Fund for Federal employees who will enter the program in fiscal year 1985. We're now hearing that rather than $38 million you may only need $4 million. That's quite a difference. What is the latest estimate, and why can't we get better estimating on this matter?

Answer: Based on actual enrollment through the end of 1983, we currently believe that we will obligate only about $2 million of the $42 million FY 1984 appropriation and about $4 million in FY 1985.

The first year that Federal annuitants and employees could apply for Medicare coverage under this provision was 1983. Our budget estimates were based on extrapolations of earlier data on Federal retirees as provided by the Office of Personnel Management (OPM). We expect to receive OPM's analysis of its 1983 data in the near future and will assess our estimating approach at that time.

Question: What effect, if any, has the new prospective payment system for Medicare had on Supplemental Medical Insurance (SMI) and the other programs under Payments to the Health Care Trust Funds?

Answer: There are two areas in which prospective payment has had an impact on Supplemental Medical Insurance (SMI) Benefits (Part B).

First, the prospective payment legislation mandated the rebundling of all non-physical services provided to hospital inpatients; that is, all non-physician services furnished to hospital inpatients must be provided either directly by the hospital or under contractual arrangements. To the extent that services had previously been paid by Part B, the rebundling change would result in some reduction of SMI outlays.

Second, we anticipate that as hospitals become familar with the prosepctive payment system some procedures which had previously been performed on either an inpatient or outpatient basis will now be performed more frequently as an outpatient service. Thus, outlays for outpatient services will be higher as a result of the incentives for efficiency under prospective payment.

## PEER REVIEW ORGANIZATIONS

Question: For fiscal 1984 we provided you with $13 million for utilization review with the understanding that this would be all that is necessary to make the transition from Professional Standards Review Organizations (PSROs) to the new Peer Review Organizations (PROs). Do you expect that all of the PROs will be in operation and functioning by next October 1--and how much will their activities cost in fiscal 1985?

Answer: We are on target with the plan. All PROs will be functioning before October 1. As to costs, we have budgeted $171 million for the review of Medicare inpatient hospital admissions during FY 1985.

Question: Isn't the PRO money appropriated automatically -- or does the House still want to have a say in the level?

Answer: The Social Security Amendments of 1983 (P.L. 98-21) authorize the direct transfer of funds without regard to amounts appropriated in advance in the Appropriation Acts--as transfers are made for benefit payments.

## MEDICAID ESTIMATES

Question: The Subcommittee notes that your budget authority request for Medicaid for fiscal year 1985 is $22.3 billion. Please explain what factors went into making up that number. Let me say, however, that we're not interested in your proposal for $1 billion in legislative savings. That's not in the purview of this Subcommittee, and we won't consider it. On the face of your numbers, it appears you will be able to save the government about $1.4 billion through carry-over funds and reductions in the State estimates. What's happening in Medicaid that allows you to make such major offsets?

Answer: The Medicaid current law request of $22.3 billion for FY 1985 is based on the State estimates submitted in November 1983 ($23.7 billion), less anticipated carry over balances from FY 1984 ($.9 billion), and an adjustment to the State estimates to reflect recent outlay trends ($.5 billion). The estimated carry over balance is based on the current estimate of expenditures in FY 1984 compared to the available appropriation. The FY 1985 request was also reduced by $500 million to reflect recent trends in actual State expenditures which have been approximately 2 percent below the State estimates. Actual outlays in FY 1983, $19.0 billion, were 2 percent below the appropriation level of $19.4 billion. Outlays for the first quarter of FY 1984 were also about 2 percent below the State estimates.

The Medicaid budget request is still developed on the basis of the State estimates, however, these adjustments were made in order to provide our best estimate of expenditures in FY 1985.

## MEDICAID

Question: Once again, you are going after absent parents to try to collect from their private health insurance for care given to their children under Medicaid. How did your actual savings for fiscal year 1984 measure up to your prediction of what you thought those savings might be?

Answer: The Office of Child Support Enforcement, responsible for the regulation implementing this provision, expects to publish the regulation in final later this spring. Thus, no savings have been garnered to date. Because of the delay in publishing the regulation, we have revised our savings estimate to $44.75 million for the remainder of FY 1984.

Question: I note that you are projecting some $325 million as rebates to the States for coming in under their cost targets for the previous fiscal year. What accounts for this seeming growth in efficiency by the States -- and are people being neglected in the rush to put attractive numbers on the balance sheet?

Answer: While the amount of incentive rebates projected to be earned in FY 1984 may be greater than the rebates earned in fiscal years 1982 and 1983, States are not necessarily more efficient in their program management, and fewer States will be getting rebates. The FY 1984 rebates represent a lower percentage of the total reductions withheld from the States than did the FY 1982 and 1983 rebates. The higher rebates for FY 1984 result from higher anticipated expenditures. We have no information which suggests that Medicaid recipients are being neglected by States because of their efforts to increase incentive rebate figures.

## MEDICAID FRAUD CONTROL UNITS

Question: I note the Administration is bringing the Medicaid Fraud Control Units under the Medicaid appropriation, but we understand that these units will be controlled by the Office of Inspector General and not your agency. What is gained by such an odd step?

Answer: The Office of Inspector General has had responsibility for these units for several years, and we see no cause to disturb an effective working relationship. However, the appropriation for the units is to be transferred to the Medicaid account so that full costs of the Medicaid program can be displayed in a single place.

## ERROR RATE STUDY

Question: The Conference Report on the FY 1984 HHS Appropriations Bill directs that the Department undertake a study of the problems measuring error rates in welfare programs and that the Department report back before hearings on the FY 1986 appropriations. Why does the Department refuse to undertake this study despite the clear direction from Congress?

Answer: First of all, let me assure you that I share your commitment to a fair and equitable quality control system designed to reduce Federal and State erroneous expenditures. The quality control system has evolved, over the last 10 to 15 years, through a cooperative process between the States and the Federal government. Furthermore, the quality control system has been the subject of numerous studies and has undergone continual refinement and review over the years. We believe that, through this process, we have successfully developed a methodology for measuring erroneous payments. It is for this reason that, after careful consideration within the Department, we determined that further study of the quality control system is not warranted.

Question: What input did you have in the decision not to do the study?

Answer: A final decision was reached after consultation with both affected agencies in the Department, the Health Care Financing Administration and the Social Security Administration.

Question: Congress listed six areas of concern including the reliability of current data on error rates and the ability of your quality control systems to get timely corrective action. By refusing to do the study, are your trying to tell us you are letter perfect in each area?

Answer: We believe that we have developed a reliable system of measuring error rates. Our system is under continual review and we are always looking for ways to improve and refine it whenever necessary. In addition, the quality control system does produce information on a timely basis, which enables the States to institute corrective action. States can and do use the quality control data on a continuous basis throughout the sample period to assist them in their efforts. They need not wait until the end of the sample period to analyze and track performance data.

## NURSING HOMES/HOSPICES

Question: The Subcommittee notes that you are requesting almost $50 million in trust funds and general funds for certification of nursing homes, hospices, and other facilities participating in Medicare. Why the increase of $10 million for this activity?

Answer: A $10.2 million increase in the FY 1985 request over the FY 1984 current level is attributable to the following factors:

1) $1.9 million is requested to survey 1,405 new providers and suppliers requesting program participation.

2) $2.7 million is requested for inflation.

3) $4.8 million is requested for increased survey coverage. In FY 1985, surveys have been expanded to cover an average of 67 percent for all Medicare facilities as opposed to 60 percent survey coverage in FY 1984. Target levels have been slightly increased for most facility types to ensure facilities with a history of noncompliance receive a survey in FY 1985.

4) $.8 million is requested for increased funding for support contracts. Increases to this category provide sufficient resources to fund an intra-agency agreement with the National Institute of Mental Health for the survey of psychiatric hospitals. In addition, other necessary contractor technical assistance will be provided for State Certification program enhancement.

Question: I recall you cut back on the hospice rates and set off a furor. Why did you decide to reduce reimbursement?

Answer: There are actually four payment rates for hospice care. These are routine home care, continuous home care, inpatient respite care, and general inpatient care. Of these, only two were reduced.

The rate for routine home care was decreased as a result of the availability of more complete data for demonstration projects reflecting a much larger patient sample. The more complete sample included patients with long hospice stays not reflected in the earlier data base. As a result, there was an increase in the average length of stay and a corresponding decrease in the average daily utilization of services. In essence, costs per day were reduced since total costs were now spread over a greater number of days.

The inpatient respite care rate was also decreased slightly, due largely to a change in the index used to inflate the daily rate to 1984 prices. The inflation factor reflected in the final regulation is a market basket index which reflects the changes in the price of goods and services purchased by skilled nursing facilities. We feel this index is more appropriate to the type of care rendered under the inpatient respite rate, since inpatient respite services are similar to those rendered by skilled nursing facilities.

Another minor change to the inpatient respite care rate resulted from the distribution of hospice interdisciplinary team costs over a longer average length of stay (indicated by more complete data) with a resultant drop in the cost per day.

It should also be noted that the two remaining rates -- for continuous home care and general inpatient care -- either increased or remained unchanged from the rates published in the proposed rule on August 22, 1983.

Question: I understand there are 1,549 institutions providing hospice type services in this country, but only 37 hospices are certified by Medicare. Why aren't there more Medicare-certified hospices -- Is it because of your low rates?

Answer: Prior to publication of final hospice regulations, HCFA canvassed the 1500 or so potential hospices to determine their interest in the Medicare hospice benefit. Over the next several months, 481 hospices responded and most of them indicated that they intended to wait until the regulations were published in final before considering applying to the Medicare program. However, upon publication of the final hospice regulations a smaller than expected number of hospices actually applied for Medicare approval.

To date, 100 hospice surveys have been completed and 44 hospices have been approved. Additionally, 4 hospices have been denied, 3 have requested a hold on the certification, and 9 hospices have withdrawn their interest either before or subsequent to certification surveys. During the rest of FY 1984 and into FY 1985, HCFA projects approximately 400-500 hospices will be certified for program participation.

We are not certain why hospices have chosen to forego, delay, or cancel their application for approval in the Medicare hospice program.

## NURSING HOMES/HOSPICES

Question: I gather the hospice movement is saving money through less need for expensive hospital services. What can you tell us about this?

Answer: While hospice does reduce hospital payments somewhat, hospital payments are not reduced nearly as much as the payments to hospices. Thus, the hospice legislation costs more money than it saves. The preliminary results for the hospice demonstration indicate that there exists a potential Medicare savings. The two main factors which would contribute to potential savings include the average length of stay in a hospice; and the provider mix of home care hospices compared to hospital-based hospices.

The preliminary hospice demonstration results indicate that the total cost of patient care per day was lower in home care hospices than either hospital-based hospices or conventional care; total cost per day was comparable for hospital-based hospice patients and conventional care patients.

The differences in cost between the settings appear to be related to inpatient hospital utilization patterns. Conventional care and hospital-based hospice patients spent more time in an inpatient setting than home care hospices.

Longer hospice stays mean lower savings. Comparison of hospice patient cost and conventional care patient costs for a fixed period prior to death revealed that home care hospice patients were less costly for all lengths of stay up to six months, whereas hospital-based hospice patients cost more than conventional care patients for stays longer than two months.

There exists the potential that the Medicare program could experience savings as a result of the hospice benefit if the majority of hospice patients were cared for in home care hospices and the average length of stay was approximately two months. There also exists the possibility that the hospice benefit will increase the cost of the Medicare program if the majority of terminally ill patients are cared for in hospital-based hospices and the average length of stay in a hospice is greater than two months. Since the Medicare hospice benefits has only been available since November 1983, it is too early to predict which of the above events will occur.

## MAXIMUM ALLOWABLE COST

Question: The Subcommittee is interested in learning the extent to which you issue new lists of drug products under the Maximum Allowable Cost (MAC) Limits Program. We understand that there have been no new MAC limits issued for some time. What can you tell us about this and with particular reference to MAC Groups 10 and 13?

Answer: The HCFA has not implemented any new MAC limits in the last two years because of the controversy that continues to surround the

Maximum Allowable Cost (MAC) program and the decision to reassess the program. The Department is currently reviewing the recommendations of a task force appointed by Secretary Heckler to reassess the MAC program. Until a decision is made regarding the future of the program, HCFA is holding off issuing any new MAC limits, including MAC Groups 10 and 13.

Question: How much is Medicaid saved by the MAC limits that have been issued--and how much in addition would be saved if MAC Groups 10, 12, and 13 were issued? Please provide a table.

Answer: The current annual savings as a result of MAC limits presently in place is $16.5 million. Additional estimated savings are:

| MAC Group | Annual Savings in millions |
|---|---|
| Current MAC Limits | $16.5 |
| MAC Group 10 | $ 2.9 |
| MAC Group 12 | $ .3 |
| MAC Group 13 | $16.0 |

Question: What has been the delay in these matters?

Answer: The delay in implementing MAC limits has been caused by the controversy that surrounds this program. In the final report issued to the President on November 14, 1980, the Health Policy Advisory Committee urged that the MAC program be discontinued. The program was later identified as a candidate for regulatory reform. While a decision was made to continue the program, continuing criticism of the program by pharmaceutical groups led Secretary Heckler to appoint a task force to reassess the program. Public hearings were conducted on September 12 and 13, 1983. The Task Force has prepared its recommendations to the Secretary and they are presently being circulated within the Department for review. All work on MAC Groups 10, 12, and 13 has been stopped pending Secretarial action on the Task Force's recommendation.

## ARIZONA MEDICAID EXPERIMENT

Question: The Subcommittee understands that there have been some problems with the Arizona Medicaid experiment which would cost about $68 million in fiscal 1985. Please tell us what is going on and what has happened to the original contractor?

Answer: In July 1983, the Arizona Health Care Cost Containment System (AHCCS) demonstration successfully completed the second round of contract awards for health care providers to provide services for the second year of the AHCCS program.

Contracts were awarded to 19 prepaid health plans to provide services for the second year. Maricopa County's plan was not awarded a contract for treatment of the State funded medically needy and indigent AHCCCS recipients for the second year. The State's contract awards were upheld when the Superior Court refused to grant the county's appeal.

The open enrollment period between August 22 - September 16, 1983 resulted in 23 percent of the 142,900 enrollees changing plans.

Arizona plans to control open enrollment more carefully in the future to curtail misrepresentations which occurred in plan marketing.

On February 24, Arizona Governor Babbitt announced that, effective March 15, the State would terminate its contract with McAuto Systems Group, Inc. (MSGI), the fiscal intermediary for the AHCCCS demonstration. The State intends to assume day-to-day management of the AHCCCS program from MSGI. The transition was necessary because the State and MSGI could not reach agreement on modifying their contract and therefore, MSGI exercised its 30-day termination right under the contract.

Question: What is being done to correct the situation and put the effort on a sound basis?

Answer: Governor Babbitt announced that AHCCS faced a $40 million deficit to the medically needy/medically indigent (which do not receive Title 19 Federal matching funds). Emergency legislation was passed which provides the State with the flexibility to restructure the adminstration of the AHCCS program, and permits the State to directly assume responsibility or to contract some or all services with an independent contractor.

The State has now assumed the full responsibility of administering the AHCCCS program from MSGI. The State offered positions to 165 MSGI employees, and over 150 accepted State jobs. The State had successfully transferred all system responsibilities from MSGI. The HCFA has worked closely with the State and offered technical assistance to assure a smooth transition.

The Governor is developing legislative proposals to address the shortfall problem. These proposals would provide a $40 million supplemental appropriation necessary to keep the AHCCCS program running through June 30, 1984; provide authority to State agency to negotiate hospital reimbursement rates on State-wide basis on behalf of AHCCCS prepaid health plans; reduce AHCCCS fee-for-service reimbursement for emergency services; provide authority to add the Federal Medically Needy program to AHCCCS and increase the amount of Federal funding available to the State; and, eliminate the period between Medically needy/Medically indigent eligibility determination and the eligibles enrollment with an AHCCCS prepaid health plan.

## PROSPECTIVE PAYMENT COMMISSION

Question: What effect, in your estimation, will the newly appointed Prospective Payment Commission have on HCFA in the next two or three years?

Answer: Since the Commission has only recently been formed, it is difficult at this early stage to assess its potential impact on HCFA two or three years from now. However, the work of the Commission will certainly be beneficial to HCFA in that it will provide the expertise necessary to assess the adequacy of the prospective payment rates. We expect the findings and recommendations of the Commission will constitute significant input into HCFA's development of the appropriate adjustments to the DRG weights and/or diagnosis related groups (DRG) classifications for FY 1986.

It is also expected that the Commission will utilize data developed by HCFA. We believe it is essential that the Commission and HCFA maintain an open exchange of information to ensure that all factors that may alter the consumption of hospital resources in any of the DRG categories are given full consideration.

Question: The Commission is responsible for reviewing DRG prospective payment rates and recommending changes in these rates. What will happen if HCFA does not agree with the Commission's recommendation?

Answer: As mandated in the law, the Secretary has the ultimate responsibility for determining the appropriate adjustment to the payment rates for each fiscal year, beginning with FY 1986. The Secretary's determination will take into consideration the recommendations from the Commission as well as from other sources (including HCFA) as necessary to ensure that the payment amounts are adequate for the efficient and effective delivery of quality health care.

Question: Your initial budget recommendation for the Commission was $1.5 million. How did you arrive at that figure?

Answer: The Prospective Payment Assessment Commission is an organization separate from the Health Care Financing Administration and from the Department of Health and Human Services. As a result, we were not directly involved in the decision made with respect to the funding level of the Commission. The Commission's budget was actually included within that of the Health Care Financing Administration for administrative convenience in terms of presentation.

## MEDICAID QUALITY CONTROL

Question: In the Medicaid program, States may be penalized for not reducing their payment error rates to the targeted error rate. However, if a State can demonstrate that it is making a "good faith" effort to correct payment errors, the fiscal sanction may be waived. As of the most recent year for which quality control data are available, how many States have achieved their target error rate?

Answer: The latest period for which final quality control data is available is October 1980 through September 1981, the first period under the Michel Amendment. For that period, 38 States met their targets for FY 1981.

Question: In how many States have fiscal sanctions actually been applied and in how many States have the sanctions been waived?

Answer: Twelve States were subject to disallowances; all have submitted waiver requests which are currently being reviewed. We are still awaiting final results from Aid to Families with Dependent Children (AFDC)

Quality Control for the period September 1981 through October 1982 in order to finalize the error rates for the second Michel period.

Under TEFRA, 15 States had actual prospective withholdings for the April 1983 quarter, 16 States for the July 1983 quarter and 16 States for the October 1983 quarter. One State had its withholding dollars reversed for the April and July 1983 quarters. However, final disallowances under TEFRA will not be assessed until actual error rate data is available.

Question: If all sanctions were applied and not waived, what would be the dollar savings to the Federal government?

Answer: The Michel disallowances would yield approximately $13.4 million in savings.

Question: What is the status of any law suits brought by the States regarding the application of fiscal sanctions?

Answer: On July 12, 1983, the States of New Mexico and Colorado filed suit in the United States District Court for the District of Columbia against Secretary Heckler. The suit requested injunctive relief from the provisions of the regulation 42 CFR 431.803 implementing section 133 of the Tax Equity and Fiscal Responsibility Act of 1982. We have been advised by Counsel that the court suit was dismissed on March 30, 1984, on the basis that the final regulation published on February 8, 1984, satisfied the plaintiff's charges.

Question: As of the most recent year for which quality control data are available, what are the most frequent causes of Medicaid payment errors?

Answer: Most Medicaid Quality Control (MQC) errors are caused by the failure of the beneficiary to report income and resources.

Question: What are the reasons the States most frequently give for failing to meet their target error rates?

Answer: States give the following reasons for failing to meet their target error rates: failure of clients to report accurate information; complex Federal requirements in eligibility and administrative areas; changes in related programs such as Food Stamps and AFDC that must be implemented within tight timeframes; and, depressed economy causing increases in the Medicaid population.

Question: Why does the budget propose to impose penalties in FY 1984 for excess Medicaid errors that occurred in FY 1981, 1982 and 1983? Why weren't sanctions imposed sooner for back years?

Answer: Data resulting from MQC reviews are available approximately two years after the review period. Fiscal year 1982 data will be available this year and FY 1983 data in FY 1985. The FY 1981 penalties under the Michel Amendment have not been taken due to the waiver requests. Waiver requests from each disallowance-liable State for FY 1981 will be reviewed during this fiscal year. After this review, appropriate disallowances will be taken.

## RESEARCH, DEMONSTRATION AND EVALUATION

Question: The Subcommittee would like to know why you are projecting relatively large increases for the Research and Demonstration function. For example, you are requesting that we provide a $4 million supplemental for fiscal 1984 in order to carry out some studies. What is so urgent about these studies?

Why are you requesting a $4 million increase for fiscal 1985 over the fiscal 1984 appropriated level? More studies?

Answer: I do not feel our requests present relatively large increases. The budget we have developed reflects a stable funding level for research, demonstration and evaluation. The one noticeable change is in FY 1984 and is related entirely to prospective payment system projects specifically requested by the Congress and in that case we were able to absorb two-thirds of them in our base.

The Social Security Amendments of 1983 mandated a series of studies related to the prospective payment system. These studies all need to be started in fiscal year 1984 in order to have the results in time to meet the due dates established in the Act. The FY 1984 budget request, which had been finalized before these studies were legislated, asked for no increase over the 1983 level ($30 million). The FY 1984 appropriation recognized some of the extra demand by assigning $1 million more than the request ($31 million instead of $30 million). We were able to reorder the work planned for FY 1984 and thereby cover the costs of 12 of the 18 studies assigned to HCFA. The remaining 6 studies are the subject of the FY 1984 supplemental request ($4 million).

The 1985 request represents no increase over the 1984 level, assuming the supplemental is granted. This is to provide the support needed to continue the required prospective payment studies through FY 1985.

## MEDICARE CONTRACTORS

Question: The next item is a request of $872.6 million in Trust Funds for the Medicare Contractors program which covers Medicare claims processing and audit and medical review of claims. Why are you requesting a $55.6 million increase for Medicare Contractors in FY 1985? (FY 1985 Request: $872,600,000; FY 1984 Appropriation: $817,000,000)

Answer: We are requesting $897.6 million for Medicare Contractors in FY 1985 plus a $20 million contingency fund. The FY 1984 appropriation was for $837 million plus a $25 million contingency. The projected increase is $55.6 million. (The total amount for FY 1984 and FY 1985 include $45 million for audits made available by the Tax Equity and Fiscal Responsibility Act in addition to the funds made available by the Appropriation Acts.)

The major portion of this increase is for claims processing, which is impacted by growth in workload volume and inflation. Part A workload is expected to increase by 12.4 percent and Part B by 11.5 percent in FY 1985. Savings from the Medicare Administrative Reform Initiative (MARI) and productivity investments offset the workload increase and inflation. We are also requesting an $8.2 million increase for payment safeguard activities, audit and medical review.

Question: Why are most contracts with these organizations of the noncompetitive type? Why don't you bid them?

Answer: The Health Care Financing Administration's (HCFA's) legislative authority under Title XVIII does not allow for competitive bidding of Medicare contracts. Only the experimental fixed price authority under section 402(a)(1)(F) allows for competition for Medicare contracts. We have used the experimental authority to competitively bid seven contracts to date.

Our FY 1985 legislative package contains a proposal to enable HCFA to let contracts on a cost or other than cost basis. This would allow HCFA to competitively bid certain Medicare contracts and negotiate the present contracts more aggressively. Significant savings could be achieved by enacting this legislation and ending the cost based methodology.

Question: What role do the Medicare contractors play under the new prospective payment system of reimbursement -- and is this costing more money?

Answer: The Medicare Part A intermediaries are responsible for the administration of the prospective payment system. They have over fifteen years of experience in Medicare claims processing and payment safeguard activities. The administration of the system uses existing billing forms, staff, and claims submission techniques to smooth the transition to prospective payment.

The implementation of prospective payment has imposed some additional cost on Medicare contractors for systems modifications and base period audit activity. In FY 1984, $7 million was specifically appropriated for contractors to conduct base period audits of all hospitals participating in the prospective payment system. The audits will be completed by the end of FY 1984. An additional $6 million was budgeted for Medicare contractor prospective payment transition costs in FY 1984.

For FY 1985, additional funding of $3.8 million has been requested to cover the exchange of data between intermediaries and Part B carriers. The funds will be used to monitor the "unbundling" provisions of the prospective payment legislation. The data exchange will prevent providers from inappropriately shifting cost. The carriers will be able to stop inpatient hospital facilities from billing for services and supplies under part B which were already covered under the diagnosis related group (DRG) payment.

## MEDICAID CUTS

Question: The 1981 Reconciliation Act made some significant changes in law that may have eliminated children from the Medicaid program and may have reduced health services as well. What can you tell us about this? How many children or young people were made ineligible for Medicaid by the Reconciliation Act?

Answer: Health Care Financing Administration (HCFA) data show that between 1979 and 1982 the number of children in Aid to Families with Dependent Children (AFDC) families served by Medicaid has actually increased rather than decreased.

| FY | Children in AFDC Families (in millions) |
|---|---|
| 1979 | 9,022 |
| 1980 | 9,285 |
| 1981 | 9,587 |
| 1982 | 9,656 |

Cuts in Medicaid eligibility for non-AFDC children have been limited almost entirely to "children" who are over 18 years of age. The majority of the States continue to cover the same groups of children covered before the passage of the Omnibus Budget Reconciliation Act (OBRA).

Question: What services for pregnant women and financially needy children have been reduced or eliminated by the States? Has there been any fall-off in prenatal care for poor women?

Answer: Our Medicaid data base does not contain expenditures for eligibles by physician specialty (e.g., obstetrical care) or by diagnosis (e.g., pregnancy). Therefore, we are unable to determine whether State programs have in fact reduced prenatal services to Medicaid-eligible women.

We would note, however, that 36 States have added coverage and reimbursement for nurse mid-wife services to their Medicaid plans. It is expected that this new type of provider has greatly increased accessibility to the full range of pre- and post-natal services available for low-income women eligible for Medicaid.

Medicaid expenditures for all services to children in AFDC families have increased 25 percent from 1979 to 1982. We suspect that this type of increase in expenditures means that more services, not less, are being provided to eligible children.

The majority of the States continue to cover the same groups of children and pregnant women as "categorically eligible" as before OBRA. For example, States may continue to cover children and first time pregnant women for Medicaid, even though they may be ineligible for AFDC.

> The Omnibus Reconciliation Act allowed States for the first time to to establish medically needy programs only for low income pregnant women and children. These two groups cannot meet the financial (income and resources) eligibility requirements of the AFDC program. Seven States, Colorado, Iowa, Mississippi, Georgia, South Carolina, Oregon, and Texas, are debating the addition to their regular programs of medically needy programs for pregnant women and children. Tennessee has an ongoing medically needy program for these two groups; however, Tennessee eliminated the rest of its medically needy program in 1983 as a result of other OBRA provisions.

Question: We need to know where the provisions of the Reconciliation Act have bitten hardest in the Medicaid program and whether, for example, infant mortality has increased as a result?

Answer: The Reconciliation Act changes to the AFDC program may have resulted in the loss of Medicaid benefits for some individuals with higher earnings. People losing AFDC eligibility, however, may be able to qualify for continued Medicaid benefits as "medically needy". In States electing this option, it would be possible to provide Medicaid once the family has incurred medical expenses equivalent to their excess income.

The OBRA also eliminated the requirement that States must cover individuals 18 to 21 if they were in an AFDC-type family (e.g., single parent). Also, if a State covered other types of children under the so-called "Ribicoff Option" (e.g., those in 2-parent families), they had to cover them up to age 21. The OBRA permitted States to set the age limit anywhere between 18 and 21. As of March 1983, of the 24 States that cover all Ribicoff children, only 7 had reduced the maximum age. Of the remaining States covering only some categories of children, 9 reduced the maximum age. Individuals 18 to 21 in AFDC-type families who lost their mandatory eligibility for cash may still qualify for Medicaid if they live in one of the 17 States that continue to cover all Ribicoff children up to age 21.

It is very difficult to assess the effects of Reconciliation Act changes on health status. We are conducting an evaluation of the overall effects of recent Medicaid changes and we will report these findings as they become available. However, the link between these changes and infant mortality is tenuous at best. Analysis of data over the last twelve years shows that there are fluctuations among States and areas each year, thus, one must look at long-term infant mortality trends and aggregates. Recent data suggests no reason for concern at this time. According to data from the National Center for Health Statistics, the infant mortality rate for the nation as a whole is declining. The rate in 1982 was 11.2, compared to 11.7 in 1981 and 12.5 in 1980.

## MEDICAID FEDERAL/STATE SPLIT

Question: I noted recent news stories concerning a recommendation by a private group that Medicaid be split into two plans. One plan would provide basic health care with uniform national eligibility standards and benefits and would be financed solely by the Federal government. The other plan would cover long-term care for nursing home residents and the mentally retarded and would be financed by both Federal and State governments. Have you seen the study and do you have any views on whether the proposed approach would improve the Medicaid program or add to its problems and costs?

Answer: The report was issued by the National Study Group on State Medicaid Strategy, which was funded under a grant from the Robert Wood Johnson Foundation. A dialogue with the States and others on ways to better fulfill the mission of Medicaid is always welcome.

We have several concerns related to specific recommendations. As you know, this Administration pursued a similar proposal in 1982 to federalize the acute care portion of Medicaid and provide a block grant for the States to manage the long term care program. Based on our experience, we believe that several areas addressed in the report still need to be further developed.

There is not enough information in this report to judge whether there would be sufficient resources to fund the acute care program. The additional recipients who would be added from breaking the tie to the categorical programs and from allowing for the medically needy option in all States would be extremely expensive. We are concerned that, without new resources, the uniform 55 percent standard could not be maintained.

The existing program currently allows for significant variation across States as to the generosity of the program. This report did not address either the equity questions or the political problems of establishing a uniform Federal limit which would require many States -- New York, California, Michigan, etc. -- to lower their eligibility standards. Serious discussion of the consequences of this change in policy and its impact on these categories of recipients must be addressed if this report is to be considered.

While it is likely that overall savings can be generated by a prepaid capitated system for acute care, the expected savings of 25 percent is far too high in our opinion. Without such savings, the cost will be higher or fewer people will be covered.

There will be considerable problems in developing reliable data to be used in determining the Federal indexed capitated percent for the long term care portion of the proposal. There is no obvious source of data, at this time, on the number of functionally impaired, developmentally disabled, and mentally retarded recipients on a State-by-State basis. Without such data, the proposed capitation system would not work.

Question: Several years ago the Administration proposed a "New Federalism" plan for taking over the Medicaid program. To what extent will this current report renew the discussion about federalizing Medicaid? (Note: The report was issued by the National Study Group on State Medicaid Strategy under a grant from the Robert Wood Johnson Foundation.)

Answer: We are always open to new ideas, especially those that would provide more for less. This new report can be used to continue our dialogue with the States on the best ways to reach our common goals.

## PROSPECTIVE PAYMENT STUDIES

Question: Your Agency conducts and supports research studies to improve the management of Medicare and Medicaid programs and to develop innovative financing and delivery systems. What kinds of special studies are you conducting or supporting this year on prospective payment reimbursement as provided by this Committee in the FY 1984 appropriation?

Answer: The Social Security Amendments of 1983 included a series of 19 studies related to the prospective payment system. Eighteen of these are assigned to HCFA; an additional study related to capital issues, is being undertaken by the Assistant Secretary for Planning and Evaluation. A list of these studies, their due dates and their status appears below:

| | STUDY | DUE DATE | STATUS |
|---|---|---|---|
| - | Skilled Nursing Facility Impact of Single Limits | 12/31/84 | Report in rough draft. |
| - | Skilled Nursing Facility Impact of Hospital Prospective Payment System | 12/31/84 | Report delay. Too soon for impact to be felt. Interim reports planned. |
| - | Including Non-US Hospitals | 04/01/84 | Under development. |
| - | Annual Impact Report, 1984 | 12/31/84 | Some work begun, add'l work planned. Support contract being prepared for award late '84 or early '85. |
| - | Annual Impact Report, 1985 | 12/31/85 | |
| - | Annual Impact Report, 1986 | 12/31/86 | |
| - | Annual Impact Report, 1987 | 12/31/87 | |
| - | Sole Community Hospitals | 04/01/85 | 1984 supplemental needed. |
| - | Uncompensated Care Costs and Large Rural Teaching Hospitals | 04/01/85 | 1984 supplemental needed. |
| - | Cost of Care Information to Patients | 01/01/85 | 1984 supplemental needed. |
| - | Part A - Part B Information Transfer | 04/01/85 | 1984 supplemental needed. |
| - | Physician Diagnosis Related Groups | 12/31/85 | Work begun. |
| - | Eliminating Rural-Urban Rates | 12/31/85 | Work planned. |
| - | Uncovered Hospitals; Long-Term Hospitals Psychiatric Hospital Units, Rehabilitation Hospital Units and Pediatric Hospitals | 12/31/85 | 1984 supplemental needed. |
| - | Diagnosis Related Group (included severity) | 12/31/85 | Work begun. |
| - | All-Payer Feasibility, Cost Shifting | 12/31/85 | Work planned. |
| - | Impact of Admission, Volume Adjustment | 12/31/85 | Add'l work planned. |
| - | Impact of State Alternative Prospective Payment System on: Medicare, Medicaid, Private Health Private Health Insurance and Tax Expenditures | 12/31/86 | 1984 supplemental needed. |

## COMPETITION

Question: What are your expectations for program savings as a result of demonstrations or alternative approaches to Medicare competition?

Answer: The Health Care Financing Administration (HCFA) is currently implementing 60 Medicare competition demonstrations designed to encourage competition among insurers and providers of health care by allowing Medicare beneficiaries a choice of alternative health plans (AHPs). The AHPs will compete for beneficiaries. The prospective payment rate will be 95 percent of what Medicare would have paid for each enrollee in the fee-for-service system. The amount is defined as the average adjusted per capita cost (AAPCC) and is derived using a method developed by HCFA's Office of Financial and Actuarial Analysis. The HCFA expects to save 5 percent of the AAPCC amount for each Medicare beneficiary enrolled in a demonstration AHP.

We expect that by encouraging competition there would be significant long-term savings in health care costs.

## MEDICARE CONTRACTING ISSUES

Question: In recent years, some Medicare contractors have expressed concern about the adequacy of budgets for audit and medical review. They have argued that additional funding in such areas produce significant program savings and are largely self-financing. How is the additional $45 million in the Medicare contracting budget for more cost audits and medical review activities being used in FY 1984? How much program savings have there been from increased activities in these areas?

Answer: The Health Care Financing Administration (HCFA) distributed payment safeguard funds, which include the $45 million from the Tax Equity and Fiscal Responsibility Act (TEFRA) in the following manner during FY 1984:

| | |
|---|---|
| Medical/Utilization Review | $ 63.4 million |
| Audit | $ 87.0 million |
| Total | $ 150.4 million |

The savings estimated to be achieved during FY 1984 from program safeguard funding is $752 million, or 94 percent of the entire Medicare Contractor Budget.

Question: What kinds of cost audits and medical review activities actually produce the greatest financial benefit to the Medicare program -- especially in light of the new prospective payment program?

Answer: Medicare audits the costs on provider cost reports based upon empirical knowledge and desk review results. Numerous issues are disclosed as a result of variance analyses, and on the basis of prior year audit findings. We have attempted to identify those areas of cost which would easily fall prey to "gaming" or "loading up" for the base period audits required to implement the prospective payment system. The areas specifically addressed include the following:

Changes in accounting practices
Nonrecurring costs
Inventories
Accrued costs and accounts payable
Capital costs
Medical education
Provider-based physicians arrangements
Unbundling
Discharges
Prepaid expenses
Allocation of costs
Reclassifications, and
Adjustments.

We are in the process of identifying similar high adjustment areas to be addressed in future TEFRA and PPS audits. We will issue specific audit protocols to address these issues. Many of the above items will be included, with additional emphasis on the following:

Cost shifting
Changes in accounting practices
Accrued costs
Passthrough costs
Prepaid expenses, and
Cost allocations.

Since inpatient hospital costs have the highest dollar value of any of the services reimbursed by Medicare, the denial of these claims has the potential for yielding the largest dollar return.

Under the prospective payment system, our medical review entities review approximately 25 percent of the cases to determine if the admission is justified.

If the admission is found to be not medically necessary or appropriate, the total DRG payment amount will be denied, thus generating large savings.

## END STAGE RENAL DISEASE

Question: In 1982, Medicare costs for end stage renal disease patients amounted to about $2 billion, or about 4 percent of total program expenditures and were continuing to grow. What impact has the change in rates for the provision of dialysis services under the End Stage Renal Disease (ESRD) program had on the rate of increase in spending for the program?

Answer: The cost estimates which were developed for the composite rate regulation are displayed in the table below. We are currently developing data that would enable us to determine what effect this regulation has had on spending for the ESRD program.

| FY | SMI-ESRD Outlay Before Composite Rate | Savings Due to Composite Rate |
|---|---|---|
| | (Dollars in Millions) | |
| 1985 | $1,845 | 255 |
| 1986 | 2,027 | 305 |
| 1987 | 2,205 | 350 |
| 1988 | 2,385 | 390 |

Question: Are there any indications that the financial incentives for renal patients to dialyze at home are working?

Answer: Yes. At the time we published the proposed regulations in February 1982, approximately 17 percent of the dialysis population was dialyzing at home. As of December 31, 1982, five months after implementation of the regulation, approximately 19 percent were dialyzing at home. However, during this same period there was another major factor at work encouraging patients to dialyze at home and the increasing popularity of Continuous Ambulatory Peritoneal Dialysis (CAPD), an alternative to home dialysis. We feel that both of these factors contributed toward the increase in home dialysis. While we cannot estimate the individual contribution of each of these factors, we feel confident that both contributed significantly to it and that the number and percentage of home patients will continue to rise over the next few years.

Question: Can you tell us how many end stage renal disease facilities have dropped out of the program since the change to the new payment system and where they are located?

Answer: Six hospital-based facilities and nine independent facilities have stopped providing outpatient maintenance dialysis treatment since Secretary Schweiker announced the new composite rate reimbursement system (and the rates themselves) to the public in November 1981.

The six hospital-based facilities were located in
California -1
Texas -2
Florida -1
New Mexico -1
Nevada -1

The nine independent facilities were located in
Florida -2
Texas -2
Virginia -1
Tennessee -1
Utah -1
California -1
Arkansas -1

It should be noted, however, that during this same period, the number of certified facilities grew by 168 to 682 hospital-based facilities and 626 independnet facilities. Most of the new facilities (156) are independent rather than hospital-based.

Question: What kinds of problems have patients had in gaining access to dialysis services as a result?

Answer: There has been a continuing interest in the question of how the new reimbursement system would affect access to care since Secretary Schweiker announced the new composite rate system (and the rates themselves) to the public in November 1981. Many predicted that hospitals would be forced out of the dialysis business and that even many independent facilities would have to close. (One large chain threatened to close 60 of its facilities.) This has not been the case.

As of November 1981, there were approximately 670 certified hospital-based facilities and 470 certified independent facilities. Subsequently, 24 hospital-based facilities have been certified, 6 hospital-based facilities have stopped providing outpatient maintenance analysis, and an additional 16 were recertified under a different provider number but continued to provide dialysis services. As of March 1984 there were 682 certified hospital-based facilities.

Additionally, 152 independent facilities have been certified and 9 independent facilities have stopped providing dialysis. As of March 1984, there were 626 certified independent facilities.

The above data indicates that there has been no reduction in Medicare beneficiary access to care. In fact, the opposite is true--beneficiary access to care has increased because of the composite rate system.

## PSROs/PROs

Question: We're concerned as to whether the new Peer Review Organizations will become operational by October 1. What effects will the delays in promulgation of regulations for the Peer Review Organizations program have on the program's implementation?

Answer: The contracting process and implementation of Peer Review Organizations (PROs) is on schedule and PROs will be in operation by October 1, 1984.

Question: Will hospitals have sufficient time to negotiate contracts with PROs by October 1, as required by law?

Answer: We anticipate no problem since hospitals will have 30 days to complete these agreements with PROs.

Question: Will potential PROs have enough time to develop their contract negotiations with providers before October 1, 1984?

Answer: We anticipate no problem since hospitals will have 30 days to complete these agreements with PROs.

Question: How are you using the information and experience gained from administering the Professional Standards Review Organizations Program in implementing the new Peer Review program?

Answer: The experience gained from administering the Professional Standards Review Organizations (PSROs) program has been taken into account in developing the scope of work for the request for proposals (RFPs) associated with the contractual process to implement the PRO program. Experience in the areas of objective setting and review methodologies has been especially helpful.

Question: Are any Professional Standards Review Organizations going to be designated as Peer Review Organizations? How many?

Answer: Contracts to PROs will be the result of competitive bidding. We anticipate proposals will be submitted by PSROs. The PSROs may also participate as subcontractors to PROs.

Question: Describe the criteria you will use to evaluate proposed contracts with Peer Review Organizations.

Answer: Our criteria have been included in the request for proposals (RFP) to afford all offerors an equal opportunity to compete. These criteria assign point values to each of the following areas included in the offerors' proposals:

1. Understanding of the work - scope and purpose of the Act, specific objectives, admission pattern monitoring, data collection, external relationships, sanctions, the review of abuse issues, and reconsiderations;
2. Objectives and review activities - proposed specific objectives (admission and quality) and approaches to accomplishing various review activities;
3. Experience;
4. Personnel, including subcontractors;
5. Management plan;
6. Physician-sponsored organizations; and
7. Price.

Question: Do you know how much the contracts with the new Peer Review Organizations will provide for in non-hospital settings?

Answer: At this point, we will not require PRO review in non-hospital settings; the initial contract with PROs will require review in acute care hospitals and a review plan for specialty hospitals. The PROs may review care rendered in other than hospital settings as part of any review they do for private organizations.

Question: Do you know how many States plan to enter into contracts with the new Peer Review Organizations to perform required Medicaid review functions?

Answer: About 25 States currently have contracts with PSROs to perform Medicaid review. States will have the same incentives to contract with PROs as they do with PSROs.

## LIVER TRANSPLANTS/MEDICARE

Question: The Subcommittee understands that HHS has declared that liver transplants are no longer considered experimental and that this may open the way for some Federal coverage for children who receive transplants. We know that your agency is acquainted with this situation since there may be some connection with Medicare. What can you tell us about it?

Answer: In accordance with the position taken by the Assistant Secretary for Health, Dr. Brandt, we are giving serious consideration to providing coverage under Medicare for child beneficiaries who require liver transplants for the treatment of biliary atresia and other rare congential liver diseases. This would affect children who are entitled to Medicare under the ESRD program.

## CYCLOSPORIN

Question: We gather that the problem -- and the cost -- involves maintaining transplant patients on a special immunosuppressant drug for the rest of their lives. What is this drug and how has your policy changed in regard to it.?

Answer: This drug is cyclosporin.

To be covered under Medicare, drugs are required to be safe and effective. Approval for marketing by the Food and Drug Administration (FDA) establishes the drug as safe and effective for purposes of this requirement. The FDA approved the drug cyclosporin as being safe and effective on November 14, 1983. For persons who are entitled to Medicare, cyclosporin is now covered when it is reasonable and necessary according to accepted standards of medical practice and the medical circumstances of the individual case to the extent permitted by the separate provisions of Part A and Part B of the program.

Cyclosporin is covered when furnished to hospital inpatients who are Medicare beneficiaries (Part A); however, outpatient drugs are covered only if they are furnished "incident to" a physician's professional service and cannot be self-administered (Part B). Two dosage forms of cyclosporin are available -- an injection and an oral liquid. Coverage of the injection under Part B would be permitted if "incident to" the physician's service; however, coverage of the oral liquid under Part B is presently precluded by the law because it is self-administered.

## LIVER TRANSPLANTS/MEDICAID

Question: It's our impression that the key to reaching -- and helping -- children who have received liver transplants is to get Medicaid to recognize care for such patients as a legitimate cost, isn't that right?

Answer: As you know, under the Medicaid law the decision as to whether to cover specific medical procedures is left to the States. However, if Medicare covers liver transplantation for children with biliary atresia and other rare congential defects, as is under consideration, we expect that a number of State Medicaid Plans will cover pediatric liver transplants as well, since a number of State Plans explicitly rely on

Medicare definitions as to which services are experimental. A number of other States may be influenced by the fact that the Department has announced that it no longer regards as experimental liver transplants for children with certain rare congenital liver diseases. The HCFA is distributing to each State Medicaid program copies of HHS' recent announcement on pediatric liver transplantation, along with copies of the report of the 1983 National Institutes of Health's Consensus Development Conference on Liver.

## FY 1983 RESEARCH ANTI-DEFICIENCY ACT VIOLATION

Question: The Subcommittee has been advised of a violation of the Anti-Deficiency Act in connection with the Research, Demonstration and Evaluation program. Please explain what happpened and what action has been taken to prevent a recurrence.

Answer: The Health Care Financing Administration's (HCFA) Program Management Appropriation (7530511) in the Research, Demonstration and Evaluation program exceeded its fiscal year 1983 apportionment by $208,921. However, since there were balances in other programs, the appropriation was not over obligated, and no funds were lost to the government as a result of this technical violation.

To assure that such a violation does not reoccur, HCFA has instituted more stringent internal funds control procedures for its Research program. The central accounting office has designed a commitment accounting system and a revised control log that the Research office will use to record all commitments/obligations. This will ensure that the Research office's control log and the computer-based accounting office commitment system will match exactly. This creates a dual-level of control where only one had existed previously. All commitment actions issued by the Research office will be reviewed and cleared for "funds availability" through the Agency's central accounting office prior to obligation. This control will provide cumulative totals of allotments, commitments and obligations, and an "available funds" balance. The control log will be readily reconcilable to the monthly accounting reports issued by HCFA's central accounting office. The central accounting office will provide the Research office with monthly accounting office reports regarding the status of commitments, obligations and balances. In addition, the central accounting office will ensure that a proper reconciliation is performed between the Research office control log and the monthly central accounting reports.

Question: We gather that two mistakes were made: there was an incorrect entry of an apportionment, and someone failed to forward a copy of a $3,500,000 research contract to accounting. Do you believe these simply were individual lapses, or did they involve fundamental control problems in the agency?

Answer: Human error in the manual posting of funding transactions to the component's control log lead to an overstated "check-book" balance. This, in turn, led to funds being obligated when, in fact, sufficient funds were not available. The component also failed to perform a timely and adequate reconciliation of its control log to the Agency's central accounting reports and, therefore, failed to note the overstatement of funds available.

The second issue is separate and distinct in that the Research component had recorded a commitment for $3,500,000 but which, the contracting office in the Office of the Secretary, failed to provide the obligating document to HCFA's central accounting office. This resulted in HCFA's central accounting office's records not showing the over-obligation. Due to a combination of unanticipated project deferrals and other contractual actions, the actual deficiency netted out to $208, 921.

## MOVE TO BALTIMORE

Question: We understand that you are moving part of your Washington staff to Agency offices in Baltimore. How many people are involved in the move -- and how many still will be located in Washington, D.C.?

Answer: We are planning to move 26 employees to Baltimore. Most of these employees work in the Division of Budget, Office of Management and Budget. Once the move is completed, approximately 150 employees will still be located in Washington, D.C.

Question: What is the reason for the move and how much will it cost the taxpayers? Will it result in the loss of any staff?

Answer: As you may know, we have been working on the development of a single site for HCFA. The move is an important step towards this goal. Because the relocated employees will be housed in our Baltimore headquarters, where space is less expensive than in Washington, D.C., the move will not involve any net expense to the taxpayer and may result in some savings, e.g., in space rental and local travel costs. Although some of the present employees may find other jobs rather than move to Baltimore, we will maintain appropriate staffing levels in affected activities.

## OFFICE OF DIRECT REIMBURSEMENT

Question: Last year our Committee was concerned that you were going to shut down the Office of Direct Reimbursement and get rid of its employees. What is the current status of ODR and what has happened to the employees involved?

Answer: Final regulations on phasing out the Office of Direct Reimbursement (ODR) were published in the Federal Register on January 30, 1984, with an effective date of February 29, 1984.

Over the next 7 months, intermediaries in the private sector will be assuming responsibility for processing claims submitted by providers who had formerly dealt directly with HCFA. Although most of the direct reimbursement workloads will be contracted out, we will continue to process claims for certain demonstration projects.

No ODR employees will lose their jobs or grade level as a result of this reorganization. An intense effort is now underway to find comparable jobs within the Agency for displaced ODR employees. I am sure that their skills and talents will be put to good use in meeting the heavy workloads imposed by TEFRA, the Social Security Amendments of 1983, and other legislative and regulatory initiatives.

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## Questions Submitted by Senator William Proxmire

### MEDICARE AND MEDICAID/SECOND SURGICAL OPINION PROGRAMS

Question: Dr. Davis, in March of last year the Department's Inspector General estimated potential savings of $157 million annually through the implementation of a mandatory second surgical opinion program. You responded in June that you were evaluating a mandatory second opinion program in Massachusetts and a voluntary program in New York. The evaluations were to be completed by September of 1983. What were the results of these evaluations?

Answer: The following is synopsis of the results of these evaluations:

### Voluntary Medicare Second Surgical Opinion Program--Blue Cross/Blue Shield of Greater New York.

In a report to Congress March 1982, we indicated that use of a voluntary second surgical opinion program (SSOP) by Medicare beneficiaries can be expected to be two percent of the Medicare beneficiaries who were recommended for elective surgery obtained second opinions through the program.

A voluntary Medicare second opinion program similar to the New York demonstation would not result in a net savings to Medicare. The program is estimated to result in a net cost to Medicare of $35 to $107 per participant.

### Mandatory Medicaid SSOP--State of Massachusetts

This SSOP has undergone important program changes over its seven year history. Findings put forth by the evaluator in 1982 indicate that this program decreased surgery rates for the targeted surgical procedures taken together with reductions varying from 15 to 30 percent across the State. The evaluator estimated that the net savings due to this program was $1 million annually.

It is likely that the final evaluation results which take into account program changes will show savings which are less than the 1982 estimate. Final evaluation results are due June 1984. This report will also address the effects of second opinion programs on beneficiaries' health status.

Question: Apparently Owens-Illinois has instituted a mandatory second opinion program for 13 types of surgical procedures including tonsil removal, gall bladder surgery and hysterectomies. The second opinion resulted in a decision not to proceed in about 8 percent of the cases. Why not initiate a limited second opinion program of this type as an interim step?

Answer: We are not familiar with the details of the mandatory second opinion program that Owens-Illinois has implemented, but there is no specific authority under the Social Security Act that would permit us to mandate second surgical opinions under either the Medicare or the Medicaid programs. As you may know, section 1801 of the Act prohibits the Health Care Financing Administration from exercising any supervision or control over the practice of medicine or the manner in which medical services are provided under the Medicare program. Section 1801 of the Act has been interpreted to preclude the possibility of mandating second surgical opinions under Medicare. Under 42 CFR 440.230(c)(2) of the Medicaid regulations the States have been given the authority to place appropriate limits on payments for a particular service based on medical necessity or utilization control measures such as second surgical opinion programs (SSOPs) that are permitted under State law. Therefore, new legislation is needed to permit national mandating of second surgical opinion programs under the Medicare and Medicaid programs.

Question: The Inspector General points out that as of March 1983 you had spent over $2.5 million to evaluate second surgical opinion programs. How much have you spent on this issue to date and how much do you plan to spend before reaching a final decision?

Answer: The Health Care Financing Administration's (HCFA's) Office of Research and Demonstrations had spent approximately $2.5 million on the evaluation of SSOPs. Pending final results from these efforts, we have no plans to commit further funds to researching the effectiveness of SSOPs at this time.

## MEDICARE - PEER REVIEWS

Question: Dr. Davis, as I understand it, 31 States will run out of funding for the support of Professional Standards Review Organizations (PSROs) by the end of May. Is that correct?

Answer: No PSRO project will run out of funding prior to the awarding of a PRO contract under the current implementation plan. Projects initially funded through May are being extended to comply with the plan.

Question: When will Peer Review Organizations be operational in the 31 States?

Answer: Peer Review Organizations (PRO) in all States will be operational prior to October 1. As indicated earlier, all PSROs will be funded until the PROs become operational within their area.

Question: (If not until later in the year) What will happen to peer review in those 31 States prior to the time that PRO funds become available?

Answer: Funding for all current PSRO projects will be continued according to our plan to award PRO contracts beginning in June. In the interim, PSROs are continuing peer review activities within their designated areas.

Question: Last year, we provided $13 million for PSRO operations in the current fiscal year. Apparently those funds will run out in May. How much do you plan to spend on PRO operations next year?

Answer: The $13 million appropriated for FY 1984 will provide PSROs with administrative costs until the awarding of PRO contracts, scheduled to begin in June. In addition, the PSRO review activities, at about $61 million, cover about two-thirds of total Medicare admissions and are funded by direct trust fund transfer. We have budgeted $171 million for PRO operations covering all Medicare admissions during FY 1985.

Question: Does your projected PRO funding level take into account the added tasks imposed by the new prospective payment system?

Answer: Yes. The projected FY 1985 PRO costs are adequate to carry out the review activities required under the prospective payment system.

## HCFA - ALCOHOL - DRUG UNITS

Question: Dr. Davis, as we both know, Medicare and Medicaid costs could be reduced substantially if this nation was able to deal aggressively with alcoholism and drug abuse in their early stages.

I understand that Secretary Heckler exempted alcohol-drug units in general from the prospective payment system until October 1, 1985, because of public concern that the proposed treatment payments would not provide for adequate treatment, particularly with regard to rehabilitative services.

The National Institute on Alcohol Abuse and Alcoholism has informed the Committee that it is working with your staff on the development of data to more accurately reflect the true costs of alcoholism treatment. Where does that effort currently stand?

Answer: In consultation with the National Institute on Alcohol Abuse and Alcoholism, the Health Care Financing Administration (HCFA) developed a plan whereby information would be obtained from Medicare bills that would permit us to more accurately measure the true cost of alcoholism treatment. The HCFA is proceeding to implement that plan.

## MEDICARE FOR PROFIT HOSPITAL ACQUISITIONS

Question: On December 22, the General Accounting Office issued a report indicating that the acquisition of a chain of hospitals and nursing homes by the Hospital Corporation of America (HCA), a for-profit health care provider, added $26 per patient day to Medicare costs and $31 per patient day to Medicaid costs at two of the acquired hospitals because of bookkeeping changes in interest, depreciation and home office expenses. Are you going to disallow these added charges?

Answer: The increased cost per patient day resulted primarily from actual higher costs for depreciation and interest incurred by HCA in acquiring the facilities in question, rather than from "bookkeeping changes." (The change in home office expenses was a decrease which served to slightly reduce the increase in costs per patient day.) We have no statutory or regulatory authority to disallow the increased costs; however, our regulations, while currently permitting increased depreciation and interest costs resulting from arms-length provider acquisitions, do provide limitations on such increases to assure their reasonableness. We are currently working with our fiscal intermediaries to assure that HCA has followed our regulations and instructions in reporting its increased costs. While it is too early to indicate the results of our review, we are in the process of finalizing further instructions to the intermediaries with respect to what action should be taken.

Question: What steps is HCFA taking to prevent the use of tax dollars to pay increased Medicare and Medicaid charges resulting from corporate acquisitions?

Answer: Currently the statute and regulations permit reasonable increases in depreciation and interest costs resulting from arms-length acquisitions of facilities. We are, however, looking at several approaches including statutory approaches to limit such increases. Further, we are reviewing our current regulations and instructions to assure they are clear and adequately express program intentions with respect to cost treatment when acquisitions occur. While no final decisions have been made, we have already identified areas where new and expanded policy instructions are needed and will be issued.

## HCFA RESEARCH

Question: When Dr. Brandt appeared before this Committee yesterday, his opening statement referred to the work of the National Center for Health Services Research (NCHSR) in these words:

> "NCHSR funds provided for the original work on Diagnosis-Related Groups (DRG's), that is, the development and testing of homogeneous patient classes from the prospective of resource consumption."

On the other hand, your justifications had this to say in describing your request for $35 million in research, demonstration and evaluation funds:

> "Research activities developed the per case payment methodology for the prospective payment system based on a Diagnosis-Related Groups (DRG's) approach."

Can you tell us who did what in the area of DRG research?

Answer: The short answer to your question is that we both worked in this area and I believe this case neatly displays the separate roles of HCFA's Research and Demonstrations organization, vis a vis NCHSR.

In the early 70's, NCHSR awarded the U.S. Public Health Service Research Grants (HS-00163-007 and HS-00090-05) to the Yale University Institution for Special and Policy Studies which resulted in "Case-Mix and Resource Use," a workpaper that was the final report for these grants, and also the title of an article published in "Inquiry", (Blue Cross Association: 1975) and later in "Economics in Health" (Aspen Systems: 1977). The first diagnosis-related group (DRG) system emerged from this work by Robert Petter, John Thompson, et al., as did the notion of possible applications of DRG's for hospital budgeting and reimbursement. However, the primary usage of this was been for hospital utilization review activity.

In 1975, the predecessor of HCFA's Office of Research and Demonstrations (ORD) awarded Contract (600-75-0180) to Yale University for "Development, Testing and Evaluation of a Prospective Case Payment System." This contract defined reimbursable cases according to clinical/demographic descriptors and the resources used. The final report is available from the National Technical Information Service.

In 1976, this ORD predecessor initiated a demonstration (Contract 600-77-0022) with the State of New Jersey Commission on Health for Prospective Reimbursement System Based on Patient Case-Mix for New Jersey Hospitals," during which both the original DRG system and the ICD-9-CM DRG System were tested.

In 1979, HCFA awarded a Grant (95-P-97499) to Yale University for development of "Diagnosis-Related Groups Using ICD-9-CM Codes." This work was most timely because the U.S. hospital section (NCHS, HCFA, AHA, BCBSA, HIAA, NAMRL) changed its standard for labelling diagnosis and procedures in medical records from ICD-8 adaptations to ICD-9-CM in the late 1970's. The five volume User Manual and related software are available from the National Technical Information Service.

Thus, NCHSR did fund the research that originated the concept of DRG's. The HCFA's ORD, and its predecessor organization, supported the subsequent research, demonstrations and evaluations that led to the completion and application of the present DRG system. The HCFA also continues to support research aimed at refining the DRG system.

The NCHSR has the responsibility for broad-based and basic research in health services delivery. The HCFA's ORD is responsible for work that is of specific use to the Medicare and Medicaid programs. This long development of our new hospital reimbursement system is a good example of the development of a concept by NCHSR which was then refined and adapted for use as a payment tool in HCFA.

## HCFA RESEARCH

Question: Dr. Brandt indicated in his opening statement that the Center's work "will be essential in assessing the impact of the DRG prospective payment system". Your justifications make reference to the Center but characterize its work as having a "secondary application" to HCFA programs. How do you reconcile these statements.

Answer: The Health Care Financing Administration's (HCFA's) Research and Demonstrations program is directed toward issues that specifically related to the Medicare and Medicaid programs. The program of the National Center for Health Services Research (NCHSR) is more wide ranging, relating to issues of health services delivery in general. We would not normally expect NCHSR to undertake a project that would have immediate application to the Medicare and Medicaid programs and that would be a task for our own Office of Research and Demonstrations. A good example is the development of the Diagnosis Reimbursement Group System for hospital prospective payment. The NCHSR funded the early research that developed the DRG concept. The HCFA went on from this work to refine the concept for use as a tool in paying hospitals, to do a demonstration using DRGs, and finally, to work out the specifics of the system we started last October. In this context we expect to see analogous work at NCHSR and HCFA. However, HCFA looks to NCHSR for basic studies/ideas that can be adapted for use in our programs.

Concerning the prospective payment system studies, NCHSR and HCFA staff have worked closely to develop a joint agenda. The NCHSR will collect a new wave of data in their Hospital Cost and Utilization Project. These data will be specifically designed to address prospective payment system issues. The data base will augment HCFA's administrative statistics in that it will have all payors, not just Medicare and Medicaid. These broad based data will indeed be "essential to assessing the impact of the DRG prospective payment system" as Dr. Brandt has indicated. The NCHSR will also conduct analyses of severity complementary to HCFA's efforts. I believe these illustrate nicely how NCHSR, with its broad mandate, can be of assistance on the specific programatic issues HCFA faces.

## HCFA RESEARCH

Question: You are requesting $35 million for research. The National Center plans to spend $17.3 million for health services research next year. Please tell us where your responsiblilities end and the Center's begin.

Answer: We see our responsibilities as directly relating to the Medicare and Medicaid programs, their current efficiency and possible changes in the future. The National Center for Health Services Research undertakes work that relates to health services delivery in general. Thus, HCFA's Research and Demonstrations (R&D) can be seen as a health services research program that focuses in detail on one segment of the population while NCHSR would fund projects that concern the entire population.

Question: Do you have a mechanism in place to insure that you are not duplicating research being supported through the Center? If so, describe it.

Answer: We have long recognized the seeming overlap of roles but in practice have found a cooperative relationship where each R&D unit can do the work most suited to its capacities and missions. The Department has a formal system whereby the research plans of the several operating divisions are reviewed by the Assistant Secretary for Planning and Evaluation. This review is specifically directed toward locating duplicative work.

The HCFA and the NCHSR regularly exchange information on the grants they are considering, prior to making awards, to be aware of duplicative applications and overlap. The NCHSR Director and the HCFA, Office of Research and Demonstrations' Director meet regularly with their peers in the Veterans Administration and the Defense Department to discuss issues of mutual concern. Finally, the professional staff of the two R&D units, having similar interests, are aware of each others work and frequently discuss it.

Question: Dr. Davis, in an article that appeared in the Boston Globe last December indicated that in some areas of Massachusetts "there are few or even no private obstetrician-gynecologists who still accept Medicaid patients unless they can pay for their care out of their own pockets. The article cited the case of a woman who lives in Plymouth but will have to travel an hour into Boston to deliver her baby because she couldn't find a local obstetrician who accepts Medicaid. One State official called the situation "close to a public emergency".

How widespread is this problem and what, if anything, can the Federal government do to correct the situation?

Answer: The Medicaid program is a public health insurer for low-income eligibles.

Two separate surveys, Intergovernmental Health Policy Project 2/82 and LaJolla 3/83 of physician participation in Medicaid show that about 160,000 physicians nationwide billed at least one service in 1982 to the Medicaid program. This represents a slight increase in the number of participating physicians since 1981. At least 4 other HCFA-funded research and survey projects on physician services have found that for the general Medicaid population, the majority of recipients are satisfied with the medical care they receive and that most recipients are able to see a physician when needed.

Physician participation levels vary by State and depend on a number of factors, including reimbursement rates, administrative paperwork, scope of benefit package and eligibility coverage, and timeliness of claims processing.

Although we have no specific evidence that accessibility to prenatal care provided by a physician is a problem for Medicaid patients, we would like to point out that Congress, through a provision in the Omnibus Reconciliation Act of 1980, P.L. 96-499, now requires States to pay for the services of a nurse mid-wife to the extent that (s)he is authorized to practice under State law. Currently, 36 States, including Massachusetts, cover these services. We expect that this new type of provider has greatly increased accessibility to the full range of prenatal and postnatal services available to low-income women eligible for Medicaid.

## MEDICARE CONTRACTORS

Question: Last year at this time you estimated Medicare Contractor costs of $820 million in fiscal year 1983. That estimated figure proved to be too high by $45.1 million. As a result, contractor cost growth between 1983 and 1984 has been revised upward from an estimate of $17 million last year to a current estimate of $87.1 million. Why was your initial 1983 estimate so wide of the mark?

Answer: The FY 1983 Medicare Contractor budget was originally estimated at $704 million. At the start of FY 1983, contractors were performing under a continuing resolution. In the first month of the fiscal year, Congress added $45 million for payment safeguards and an additional $51 million for claims processing and productivity investments. Because the contractors had been operating at a reduced level in FY 1982, the FY 1983 claims processing and productivity investment funds were used to hire additional staff. The buildup of these contractor resources required considerable time to implement but at the same time the contractors were unable to absorb all of the additional claims processing and productivity investment funds.

In FY 1983, $775 million was obligated from a budget of $800 million, which excludes the contingency fund. The contractors did expend all the additional funds which Congress had earmarked for payment safeguards.

## HOSPICE REGULATIONS

Question: On December 16, 1983, the Department of Health and Human Services published final hospice rates which were much lower than originally proposed for public comment in August 1983. HHS said, it will evaluate the impact of these final rates on the operation of hospice programs operating before the December 16 rates became effective. I am pleased to hear that. But in the meantime, I remain concerned about the impact of the published rates on existing and planned rural hospice programs.

In my State of Vermont, hospice programs are operated by the Home Health Agencies, and they are telling me the current rates, and other regulations, do not take into account rural needs and characteristics. I would appreciate your consideration of the following questions:

## HOME HEALTH CARE

Question: Dr. Davis, as you know, the policies of Region V and its fiscal intermediaries interpreting the intermittent home health care benefit have been subject to severe criticism by Medicare beneficiaries and home health agencies in my State. Because of the depth of this criticism, which is leading to criticism of Congress' motives in adopting the DRG system, I feel it is necessary to have you answer for the record a series of detailed questions in this area.

When a home health care agency receives a request for home health care for a Medicare beneficiary, what documentation is required of the certifying physician before the agency initiates service?

Answer: The home health agency (HHA) is required to obtain a physician's order to evaluate the patient for home health services. This order may be obtained verbally and later signed by the physician.

## RESPONSIBILITIES OF PROVIDERS

Question: Has HCFA's Region V office or its intermediaries conducted educational programs with physicians in Wisconsin so that they understand the basis on which the fiscal intermediary will interpret the "reasonableness" or "medical necessity" for intermittent care?

Answer: No educational programs have been conducted for physicians in Wisconsin by HCFA Region V or its intermediaries.

Question: When a home health agency (HHA) receives physician certification that a Medicare beneficiary requires home health services, what procedures are they required to follow before initiating service. Specifically, are they required to "second guess" the physician's judgment on medical necessity of care? If so, must this HHA review be conducted by another physician, or is it based upon guidance from HCFA or the intermediary? Can you provide an example of the guidance provided?

Answer: When an agency receives the physician certification or verbal order for home health services, the agency is required to perform an evaluation visit for the patient. During this visit the agency nurse must consider the homebound status of the patient, the physical facilities, and attitude of family members to evaluate the feasibility of meeting the patient's medical needs in the home setting. The agency must also evaluate whether the patient care requirements would meet Medicare guidelines and are the type for which payment may be made.

The decision whether to accept the patient for home health services under the Medicare provisions resides with the agency, based on guidelines provided by HCFA. While they are not actually "second guessing" the physician's judgment on the medical necessity of care, the agency is more familiar with the program requirements and with the coverage requirements than the physician.

The Medicare Health Agency Manual contains basic guidelines and definitions of the services for which program payment may be made. For example, Section 218.3 specifies that the agency must have written policies concerning the acceptance of patients by the agency. The manual also explains the purpose of the validation visit and the payment mechanisms of such visits.

Question: If home health agencies are required to rely upon their experience with prior claims, this would appear to result in a haphazard guidance system for the agencies. What steps has HCFA or its intermediaries taken to assure that all agencies will have in writing the same guidance, updated as new precedents are set? If this has not been done, do you intend to take such steps? If not, why not?

Answer: The Health Care Financing Administration (HCFA) provides written guidelines and definitions to all participating home health agencies. These guidelines are revised and updated when new policies are formulated or when there needs to be clarification of existing policies. In addition, HCFA intermediaries provide written instructions to the providers in the form of bulletins or newsletters on an as-needed basis.

Question: When a claim is reviewed by a fiscal intermediary, what requirements are established by HCFA for the individuals permitted to conduct medical reviews during the claims review process? Does HCFA permit non-physicians to review the medical necessity of claims? If dentists, nurses or non-medical personnel are permitted to conduct such reviews, why do you feel these individuals are qualified to conduct such reviews?

Answer: The HCFA contracts with intermediaries require that the intermediary review provider bills and make correct coverage determinations.

The HCFA does not specify the credentials of the reviewers. It is accepted practice that intermediaries employ non-physician medical personnel to review provider bills. Each intermediary utilizes nurses, physical therapists, laboratory technicians and paramedical personnel to perform claims review. These individuals are trained specifically in the Medicare program guidelines and are used at the level of expertise they possess. All intermediaries maintain a physician consultant to review complex cases and act as advisor/reviewer as needed.

Question: If non-medical personnel or non-physicians can conduct medical necessity reviews, how does this differ from the initial determination of medical necessity, which is required to be conducted by a physician? If there is no substantive difference, is there a real need, aside from statutory requirements, for the initial determination to be conducted by a physician rather than a nurse practitioner, for example?

Answer: The decisions made by the intermediary reviewers on the coverage status of home health services under the Medicare program do not affect nor reflect on the physician's decision that the patient needs care. The intermediary determines whether the care required meets the Medicare requirements (e.g., skilled, intermittent, homebound, etc.), not whether the patient needs care.

The statutory requirements that a physician order care is in keeping with the thrust of the Medicare program; that is, Medicare is a medical program and the physician should be the person to order care.

Question: If a claim is disapproved based upon a fiscal intermediary's determination that the physician's determination of medical necessity was incorrect, what is the appeal process that is followed? How does the agency determine whose judgment is correct?

Answer: The appeals process may be an informal review where the agency submits additional medical information and requests a re-review, or it may be a formal request for reconsideration. The issue is whether the services and needs of the patient meet the Medicare requirements and not whether the physician's determination of patient requirements was correct.

The intermediary will provide the rationale for the denial to the agency so that the agency may rebut the decision or apply the rationale to future cases in order to learn application of coverage guidelines.

If, after reconsideration, there is at least $100 minimum at issue, the beneficiary can request a hearing before an administrative law judge (ALJ).

If, after the ALJ hearing, there is at least $1,000 minimum at issue, the beneficiary may request judicial review.

The appeals process is available to the provider if the provider was assigned liability for the noncovered care, and the beneficiary is not pursuing his appeal rights.

Question: If a claim is disapproved solely because the intermediary rejects the physician's determination of medical necessity, who is legally responsible for the payment for the services provided? The beneficiary? The physician? Or must the home health agency absorb the cost?

Answer: If a claim is disapproved it is because a specific Medicare guideline was not met and is not a rejection of the physician's determination of medical necessity.

Usually, the Medicare program assumes liability for the cost of the noncovered services. However, when it is determined by the intermediary that the provider knew or should have known that the services were not covered, the agency would be held liable. Only when the beneficiary is not homebound or knew previously that such care would not be covered, will he/she be held liable for the cost.

Question: If it is the physician's determination that is in question, why should Congress not make certifying physicians legally responsilble for the costs of services provided under their orders if HCFA truly believes the certification to be inaccurate? Would this not decrease improper certifications? Would you support such a legislative change?

Answer: We already hold physicians and providers legally responsible for care that is not covered under Medicare by denying payment for the physicians' fees or the providers costs for such care. In only one instance can payment be made for noncovered care. This is when a physician or provider acted in good faith to provide care that was later determined to be unreasonable or unnecessary (for example, the care provided was custodial in nature). If the physician or provider could have reasonably been expected to know such care was not covered (for example, because of previous denials which might have been paid under the waiver provision), then the costs of care are denied to providers and to physicians who accept assignment of their Medicare claims.

We support the elimination of the waiver of liability provision for providers, but believe we can effectively deny most noncovered care provided by physicians by reviewing each bill and rebutting claims that the physician did not know the care would not be covered.

## INTERMITTENT HOME HEALTH CARE

Question: Wisconsin Medicare beneficiaries and providers claim that our fiscal intermediary has established a standard for 'intermittent care' of 3 days per week, 3 weeks maximum unless stringent 'medical necessity' standards are met. Is this correct? Does this guidance originate from

HCFA? What is its legislative basis and has it been promulgated as a rule with the possibility of public comment?

Answer: The Health Care Financing Administration (HCFA) has not established national standards limiting "intermittent care" to three days per week, three weeks maximum. Our current guidelines permit 2 to 3 weeks of daily care with additional daily care permitted based on physician documentation of need. The statutory basis for the intermittent care requirement is section 1861(m)(1) of the Social Security Act which defines home health services as including part-time or intermittent nursing care and sections 1814(a)(2)(D) and 1835(a)(2)(A) which specify that an individual is eligible for home health benefits only if there is a physician certification that the individual requires skilled nursing care on an intermittent basis or physical therapy or speech therapy. This requirement was promulgated in Federal regulations at 42 CFR 405.1633 and 405.236 many years ago with full opportunity for public comment.

Question: How does this guidance compare with that issued in other regions? Have any HHS regions issued different guidance? Which guidance most reflects HCFA's interpretation of the statute as it now exists?

Answer: The HCFA regional offices periodically provide guidance to intermediaries in their region in response to questions or special situations in their area which require attention. Regions generally consult with central office staff to assure that their guidance is not inconsistent with national policy.

Question: Do you believe that care can ever be provided on a daily basis (for example, 7 days per week for 3 weeks duration) under current statutory authority? Please provide for the record several examples of cases which would meet the necessary medical necessity standard if this is possible.

Answer: Certainly, given that all other coverage requirements are met, the Medicare intermittent care requirement has been interpreted to allow payment for a short period of daily care which would include a case in which care was provided 7 days a week for 3 weeks duration. In fact, our current manual guidelines to intermediaries explicitly authorize payment for such daily service for a short period of time. However, such daily services must be medically necessary and not be projected to go on for an indefinite period of time. There are a wide range of cases in which such care may be needed, for example many complex post-operative care patients would qualify for such care.

Question: Under your interpretation of "intermittent" can cases arise in which the intermediary agrees that the individual requires medical care (but not SNF care) for a duration of 45 days or more but would refuse any reimbursement at all? What should Federal policy be in this area? Should the beneficiary be covered for whatever time frame HCFA considers the limit under the "intermittent" standard and the beneficiary should then assume financial responsibility from that point? Home health agencies allege that if that occurs the intermediary is denying any reimbursement at all. Is that your interpretation of what should happen?

Answer: We are presently providing reimbursement for daily skilled nursing services under the home health benefit where it is projected that such services will be needed for a short period of time. We do not believe we can reasonably extend this broad interpretation of the statutory intermittent care requirement to situations where it is clear that daily care will be needed indefinitely. Therefore, if it is clear from the outset that a patient will need daily skilled services indefinitely, we do not believe we should undertake payment for daily services as if there were the genuine expectation that the intermittent care definition will be satisfied after a short period. As I have mentioned previously, our current guidelines do allow additional daily care based on physician documentation of need.

Question: If you believe any Medicare reimbursement is improper in the case just cited, are we not then creating a class of Medicare beneficiary being denied home health care after a hospital discharge? It would appear that the sickest patients upon discharge from a hospital would receive SNF care, those with limited needs would receive (in Region V) up to 3 weeks care and those unlikely enough to require a longer period of care would not even receive 3 weeks of reimbursement. They would receive nothing at all. Do you believe that is fair or accurately reflects Congressional intent? Does the statute need to be clarified so no class of Medicare beneficiary (where medical necessity is present) will be summarily denied care? Would you support such a change?

Answer: As discussed in my response above, we believe that in allowing payment for daily skilled nursing services for a short period of time (which may extend beyond 3 weeks in certain circumstances) we have adopted as broad an interpretation of the statutory intermittent care requirement as administrative discretion allows. This does mean that there are patients discharged from hospitals who need skilled nursing care on a daily basis for an indefinite period of time who are not covered under the Medicare home health benefit. Generally, these are individuals for whom coverage would be available in a skilled nursing facility but who do not receive this care for a variety of reasons, including personal choice. While it can be argued that this creates an "unfair" gap in Medicare coverage, I believe HCFA's interpretation is consistent with the statute. Studies (such as GAO Report IPE 83-1, "The Elderly Should Benefit from Expanded Home Health Care But Increasing These Services Will Not Ensure Cost Reductions") point out that providing intensive home services over an extended period of time is extremely costly and may exceed the costs for already expensive institutional care system. Because of this we cannot blanketly endorse expansion of the home health benefit in this area.

## SUPPLEMENTING THE MEDICARE BENEFIT

Question: As I understand your final DRG regulations, they permit Medicare patients in hospitals to supplement their Medicare benefit by purchasing out-of-pocket an additional day of care if they feel it is necessary but it is beyond what the hospital deems essential. Yet in this area, your intermediaries are denying Medicare home health care patients the right to supplement the home health care which Medicare would provide the additional care purchased on their own. Is this HCFA's interpretation of the law or are the intermediaries misinterpreting your intent? If this is accurate, provide for the record an analysis of the statutory language that permits such out-of-pocket purchases in the case of the hospital DRG benefit yet denied it in the case of the intermittent home health care benefit.

Answer: Medicare beneficiaries are permitted to supplement their Medicare benefit by purchasing additional care which is not medically necessary under both the DRG regulations and home health benefit. However, because of the intermittent care requirement under the home health benefit, we believe patients who actually need daily skilled nursing services for an indefinite period of time but who pay for enough of this care out-of-pocket to give the appearance of needing only intermittent care may be viewed as not satisfying the intermittent care requirement under the Medicare program. Patients are not prohibited from purchasing additional care but rather may jeopardize the coverage of the balance of their home health services under Medicare, if the intermittent care requirement can be viewed as not met. We are presently reviewing our policy in this area and have asked our legal advisors for an opinion on this matter. When we finalize our policy we will be providing appropriate instructions for our intermediaries.

## PROVIDER FRAUD AND ABUSE

Question: Please summarize for the record your Department's findings regarding fraud and abuse in home health care services reimbursed by Medicare. To what extent does this abuse lie with certifying phyisicans, home health agencies or Medicare beneficiaries and do you believe these statistics are methodologically sound?

Answer: Valididation reviews conducted on 24 home health agencies (HHAs) in four States and Puerto Rico resulted in identification of $85 million in over payments. Major findings included: unreasonable costs associated with management service contracts; unallowable costs related to patient solicitation; unreasonable salaries for administrators, medical directors and nurse supervisors; overutilization; and, non-homebound patients.

Seven audits have identified $353,400 in unallowable costs.

A summary of specific problems currently existing with home health care services are as follows:

### SUMMARY OF PROBLEMS

A. Retrospective cost reimbursement has been under fire for several years because the system provides no incentive to control costs. Over the years, the retrospective system has encouraged practices on the part of the provider community which have increased costs while not necessarily improving patient care.

B. Currently beneficiaries must be homebound in order to be covered for home health services under Medicare. Interpretation of the homebound requirement varies among intermediaries. The guidelines state that the "condition of these patients should be such that there exists a normal inability to leave home and consequently, leaving their homes would require a considerable and taxing effort." In practice, patients may nevertheless be considered homebound, provided outings are infrequent or for periods of relatively short duration. HCFA should tighten the definition of homebound status to such a degree that there is little or no room for discretion. Policy should be revised in such a way that contractors have specific manual references to cite in denying a claim.

C. Intermediaries and State agencies are allowing compensation and fringe benefits under the Medicare and Medicaid programs which are abusive and in some cases fraudulent. These costs are being allowed because present policy allows intermediaries to reclassify costs as compensation for providers without even obtaining a statement from the provider that they wish to have the expense treated as compensation. For example, a provider pays for a trip to Europe for an Administrator and classifies the expense as travel and entertainment. Upon audit, it is determined that the expense is not an allowable expense for travel and entertainment because it is personal and not related to patient care. According to HCFA policy instructions, this item need not be disallowed. Instead, it can be added to the Administrator's compensation and would be allowable to the extent that the total paid plus this amount did not exceed reasonable compensation. The provider never has to demonstrate that the expense was originally intended to be compensation or a fringe benefit. These amounts may not be reported to the Internal Revenue Service as a part of the Administrator's compensation, nor reflected in the provider's books as compensation, nor reported to any other third party source as compensation.

D. The major cost category contributing to excessive program payments involves administrative salaries. Salary costs represent 80 percent of total home health agency costs. The administrative salary costs average 50 percent of total personnel costs or 40 percent of total costs. This means that for every dollar paid for professional nursing care another dollar is spent for administrative salaries. The duties of administrative personnel often overlap and involve nonpatient care services such as solicitation and public relations.

E. Under current law and policy, durable medical equipment (DME) furnished to HHA patients may be reimbursed by Part B or Part A of Medicare. Part B reimbursement occurs when the DME supplier bills Part B directly for any equipment provided to HHA patients. Part A reimbursement occurs when DME is paid through the HHA. This occurs in one of two ways: (1) the HHA may own DME used by patients; or (2) the HHA can "arrange" with a DME supplier to provide the needed equipment. Greater program payments are made for DME "arranged" through HHA because:

(1) There is no co-pay requirement;

(2) It is not feasible for Part A intermediaries to scrutinize claims (or costs) for DME in the manner of Part B carriers in order to prevent payment for deluxe items, contraindicated items, noncovered items, etc., or to limit payments to the Part B allowance for similar items; and

(3) There is no mandated lease-purchase requirement for DME rented under arrangement via Part A. The HHA Manual touches on the DME purchase subject only if the patient is receiving home health benefits under Part B. Consequently, less expensive DME items that will only be purchased under Part B will continue to be rented through HHAs.

A recent paper prepared by our Dallas Regional Office also details many of the same types of problems being encountered with home health care services nationwide. The Region VI report sets forth their general experiences with HHA operators and contains a summary of the region's current HHA case work. General findings indicate that a large number of noncovered visits are being conducted by those HHAs reviewed along with a variety of abusive practices that facilitate the provision of these uncovered services. These findings include: the existence of a massive volume of noncovered nurses', nursing aides', physical therapists' and speech therapists' services; unnecessary nurse visits to those not in need of intermittent skilled care or provided in order to qualify for aide visits coverage; care provided without benefit of specific written plan of care by physician; intentionally altered clinical notes and physicians' orders to support appearance that a covered services were provided and to increase number of ordered visits; altered travel records to conceal agency staff time spent on noncovered activities; forged physicians' signatures by agency staff to indicate conducted visits ordered by a physician; reimbursement by intermediaries at interim rates in excess of established per visit upper limits; and, unlicensed nurses providing care that was later claimed as skilled care.

The Region VI report suggests the existence of significant overpayments to HHAs in the region and indicates that 50 percent of the reimbursement claimed by HHAs in that region may be in error. A copy of this report has already been forwarded to the Regional HCFA Administrator in Dallas for review and comment.

## PROVIDER FRAUD AND ABUSE

Question: How do these findings compare with post audit findings? Are these statistics comparable? If not, why not?

Answer: In order to assure coverage, HCFA intermediaries establish pre- and postpayment review practices. Prior to payment, claims must pass screens established to detect inappropriate utilization. Within the past 2 years, this prepayment detection system has been reinforced with a postpayment onsite audit process.

While both the prepayment screening process and the postpayment audit activity has had extremely limited effectiveness, we believe problems found in HCFA post-audit reviews are similar to those findings outlined in our Region VI report. The HCFA should compare the problems contained in that report and verify these various findings.

Question: Does HCFA require any additional statutory authority to limit existing fraud and abuse?

Answer: Various legislative proposals are being recommended by the Office of the Inspector General (OIG) to address ongoing problems encountered in the provision of home health care services.

One legislative method being considered is to limit inflated salaries and other home health costs presently passed on to Medicare through a prospective reimbursement rate based on units of service for all HHA treatment.

A proposal currently contained in our FY 1985 legislative package would initiate a cost sharing provision for all items of durable medical equipment furnished as a home health care benefit.

In addition, legislative changes are being considered to address the handling and intent of physicians' care and the appropriateness of these services.

## THE HEINZ INTERMITTENT CARE PROPOSAL

Question: Senator Heinz has introduced legislation to statutorily establish a definition of intermittent care at 60 days on a daily basis. Do you support this proposal? What is your estimate of the cost of that proposal? Please provide for the record the assumptions underlying your actuaries assumptions.

Answer: We believe our current guidelines, which permit 2 to 3 weeks of daily care with additional daily care permitted based on physician documentation of need, to be sufficiently flexible to meet the intent of the statute that home health care be provided on a "part-time or intermittent" basis. We cannot support legislation which would increase Medicare Trust Fund expenditures at a time when the trust fund's viability is threatened.

However, we have estimated the cost of the proposal. The estimated impact using an October 1, 1985, effective date is as follows:

Cost in Millions

| FY'85 | FY'86 | FY '87 | FY'88 | FY'89 |
|---|---|---|---|---|
| $25 | $30 | $30 | $30 | $35 |

The actuarial estimates were derived as follows. The data source used was the Home Health 40 percent Non-Diagnostic Bill File for the first 6 months of 1982. From this data source, we were able to develop a distribution of home health bills for daily users. This was done based on the "from" and "to" date on the bill record and the number of nursing care visits and aide visits reported on the bill. We assumed that every bill with 10 and under daily visits would not be affected. From the distribution, we determined that one-half percent of all bills had 15 visits and one and one-half percent of all bills had over 15 daily visits. Based on the distribution, we estimated that the 10 to 15 group would generate on the average 15 extra visits, while the over-15 group would generate an average of 30 extra visits.

Question: How would those estimates change if the limit was set at 45 days? Thirty days?

Answer: The following is a comparison of the 45 day limitation versus the 30 day limitation.

| FY | 45-Day Limitation | 30-Day Limitation |
|---|---|---|
| 1985 | $20 | $15 |
| 1986 | 20 | 15 |
| 1987 | 25 | 20 |
| 1988 | 25 | 20 |
| 1989 | 25 | 20 |

Question: How would those estimates change for all three limitations (60 days, 45 days, 30 days) if frequency per week were limited to three days by the beneficiary were clearly permitted to purchase additional care (either during each week or beyond the hypothetical duration limits) out-of-pocket?

Answer: We have not completed any cost estimates for those proposals.

## HEALTH MAINTENANCE ORGANIZATIONS

Question: What is the current status of your regulations implementing the TEFRA provision designed to encourage Medicare beneficiary enrollment in health maintenance organizations (HMOs)?

Answer: Proposed regulations to implement this provision of TEFRA were signed by the Secretary of DHHS on March 27 and went to OMB on March 28.

Question: There have been reports that OMB has held up the regulations due to concern over the financial consequences of "adverse selection" for the government. What is your current estimate of the costs or savings involved in implementing this provision of TEFRA? How does it differ from OMB's determination?

Answer: We do not believe such reports are correct. As indicated in answer to the previous question, OMB has had the regulations for review for less than a month. The HCFA's actuaries estimate that program costs will increase when the regulations are effective as follows: For FY 1985 $30 million; for FY 1986, $65 million. The primary reason we expect these estimated cost increases to occur is that we assume that, in the absence of these regulations, the Medicare program would save more from beneficiaries' enrollment in HMOs under cost contracts. We are not aware of an OMB estimate.

Question: How many States have sought to use their 'freedom of choice' waivers to channel Medicaid recipients into HMOs?

Answer: To date, 11 States have submitted freedom of choice waivers to channel Medicaid recipients into HMOs, as follows:

- California
- Colorado
- Hawaii
- Massachusetts
- Michigan
- New Hampshire
- New York
- Ohio
- Pennsylvania
- Utah
- Wisconsin

o Of those eleven States four have withdrawn requests.

- California
- Hawaii
- Massachusetts -(State requested program be terminated.)
- Ohio

Colorado has not implemented one of its approved programs which includes use of HMOs.

New Hampshire asked for a 1903(m) waiver to restrict recipients' ability to disenroll without cause for a period of 6 months. The waiver was not implemented.

New York requested a 1903(m) waiver to require that new Medicaid enrollees in an HMO remain in the HMO for a minimum enrollment period. Only two HMOs were involved, with a total of 71 recipients. The State does not plan to request waiver continuation.

Pennsylvania requested a waiver of three provisions of 1903(m) to implement a case-management system. This has not been implemented. Three of the four organizations originally interested have removed themselves from consideration in contracting with the State.

Michigan requested a 1903(m) waiver so that it could lock-in its Medicaid HMO and PHP enrollees for a six-month period following enrollment. The State has found that after an initial adjustment period, its Medicaid enrollees believe that HMOs (and PHPs) provide them with improved access to care. Seven HMOs are participating.

Wisconsin requested a 1903(m) waiver to lock-in recipients to an HMO for a minimum period of six months. There is very little data available.

Utah did not request a 1903(m) waiver. The State HMO option was approved as part of its case-management program.

Question: The Congress has repealed (inadvertently, in my opinion) the authority the States had been given which would enable them to enroll Medicaid recipients in HMOs prospectively for periods longer than 30 days. Do you believe that we should reinstate that authority?

Answer: The authority for States to guarantee Medicaid eligibility for up to six months for recipients in HMOs has remained the same. The Tax Equity and Fiscal Responsibility Act of 1982, however, repealed the Secretary's authority to grant States waivers of certain HMO requirements, including the ability to "lock-in" Medicaid recipients into alternative health care delivery programs set up by the States. Thus, recipients can disenroll from such programs on one month's notice. Several States have complained that deletion of this waiver authority is hindering their abilities to develop cost-effective health care delivery alternatives. The HCFA will be reviewing this and other recent legislative changes in the Medicaid program. At the present time, we have no recommendations for statutory changes in the waiver authority.

Question: It is my impression that States are in a better position to determine different capitation rates for classes of Medicaid recipients (such as the AFDC population, the disabled....) than the Federal government is in the case of Medicare beneficiaries? Is this correct? Are studies underway to improve that data base?

Answer: State Medicaid agencies do determine the capitation rates for their contracts with HMOs. However, we believe the Federal government is in the best position to determine, pursuant to Federal law, capitation rates for Medicare contracts with HMOs. The HCFA does have studies underway to look at the system for determining capitation rates, which include data bases. Although no mechanisms are under consideration to replace the present sysem we are investigating modificiations to the current formula.

## HEALTH MAINTENANCE ORGANIZATIONS

Question: Would improved data by class (age, sex, health status) provide a better basis for HMO reimbursement by Medicare than the average annual per capita cost (AAPCC) which is currently in place? Are alternative reimbursement mechanisms under consideration to replace AAPCC? Would alternative measures better reduce the probability of "adverse selection"?

Answer: Improved data by class (age, sex, health status) would not provide a better basis for HMO reimbursement by Medicare than the one which is currently in place (age, sex, welfare status, institutionalized status). We are currently not adjusting the AAPCC calculation for health status for several reasons: The open enrollment requirements should create a representative mix of health statuses. Given that all applicants must be accepted, and given the age of the population, there is currently no insurance industry system for quantifying the effect of health that meets the needs of the AAPCC calculation.

No mechanisms are under consideration to replace the AAPCC approach (use of underwriting factors), but we are investigating modifications to the current AAPCC formula.

The HCFA is investigating the use of two measures available from administrative records for inclusion in the AAPCC. They are former receipt of SSA disability benefits and Medicare utilization prior to joining an HMO. Before adopting any changes to the AAPCC, HCFA would have to be sure they are practical, they increase the accuracy of the AAPCC, and, most importantly, do not open up possibilities of even worse forms of adverse selection.

## COMMUNITY NURSING CENTERS

Question: Legislation has been introduced to provide for Medicare reimbursement of community nursing centers. What are community nursing centers? Do you know how many centers exist? Has the Department developed any cost data regarding such centers? Do you plan to conduct any studies or demonstration projects in this area?

Answer: As we understand the provisions of S.410, the proposed Community Nursing Center Act of 1983 would create a new provider defined as freestanding, public or private organization primarily engaged in providing nursing services directly to at least two of the following groups: those who meet the requirements for Medicare home health services, those who are currently in institutions or who have been institutionalized for at least 30 days in the last two years or who are determined otherwise to have no reasonable or feasible alternative to insitutionalization, and infants and other children in need of well-baby or health supervision services. Other services that must be provided include physical, occupational and speech therapy and social services supportive of the overall nursing plan of care. The plan of care may also include the use of home health aides, certain medical supplies (excluding drugs), well-baby services and related supportive services to prevent the need for insitutionalization.

Since the bill would create a new provider with specific organizational and service delivery requirements, we do not know how many existing organizations woud be capbale of meeting these requirements. Similarly, since such providers are being established under this bill, we do not hve any data on them.

We are conducting a number of demonstrations in home and community-based care whose aim is to provide a broad array of social and health care services to avoid institutional care. These include the channeling demostrations being conducted by the Department, other home and community-based care demonstrations that are now being evaluated by HCFA, waiver program being implemented under Medicaid to provide home and community-based services and the social health maintenance organization demosntration which is currently under discussion.

## ALTERNATIVES TO HOSPITAL-BASED CARE

Question: There has been an explosion in new sites for health care in the last few years including such sites as surgicenters, emergicenters, Doc-in-a-Box, etc. Please review, for the record, Medicare's current reimbursement policies to these new centers for care.

As these centers proliferate, what is the Department's best judgment regarding the cost implications for Medicare now that we are moving toward a fully implemented DRG system? Will they reap windfall profits from Medicare due to lower capital costs by receiving the full DRG price? Will there be a different price schedule for these centers?

The DRG system is predicated on the "law of large numbers." Hospitals will make money on some cases and lose money on others. With increasing percentages of lower risk, routine surgery and care moving to non-hospital sites, how will this shift the assumptions of the DRG payment system?

Answer: In our judgment, the growth in new sites for health care should improve the efficiency of health services delivery and not adversely impact upon Medicare's costs.

Medicare Part B will pay only procedure-based reasonable charges for the covered items and services delivered to beneficiaries in these sites. The only present exceptions to this are the participating ambulatory surgical centers or "Surgicenters" and the rural health clinics. The former are eligible to be paid a facility allowance in addition to procedure or service allowances. The latter can participate on a cost per encounter basis or a service fee basis. Previous research on "Surgicenters" suggests that the types of cases they treat mainly involve the under-age-65 population. This also appears to hold true for most kinds of new sites for health care. The HCFA does not now, nor does it intend to pay the full DRG price for ambulatory care cases. Research is continuing, however, in designing prospective payment systems for ambulatory care.

It should be recognized that the growth of new sites for health care began prior to either TEFRA or the Medicare prospective payment system

(PPS). These enterprises have been successfully competing on a price basis despite the fact that Medicare and many other payers do not differentiate benefit payments between care in these sites and care in ordinary doctors' offices. Their growth reflects the patronage they have been able to attract by combinations of convenience, satisfying care and affordable out-of-pocket prices.

At the extreme, a problem might arise if, for a particular DRG, hospitals treat most of the harder, resource-intensive cases and non-hospital sites treat the easier, less-resource-intensive cases. In such cases, the DRG's prospective payment rate may not cover the average hospital's average case costs. On the other hand, the hospital might attempt to avoid such a problem by such actions, as:

1. opening its own "Surgicenter" to earn the profits of easy cases.
2. enrolling potential patients in its area into its own HMO to capture the easy and the hard cases together.

The PPS system will be watched closely to determine whether unintended hospital behavior is occurring so that corrective action may be taken, such as recalibration of specific DRG rates, or extension of PRO-type activity to non-hospital care.

## MANDATORY SECOND OPINIONS

Question: In response to a question you referred to optional second opinion programs for elective surgery for Medicare beneficiaries. What is the current status of that program? How many Medicare beneficiaries have sought a second opinion? How many subsequently choose not to have surgery?

Business leaders have indicated to me that in their firms the only effective second opinion program is a mandatory one; optional programs are erratic in performance. Is this a correct reading of the literature in the private sector? Why should this successful approach not be adopted by the Federal government?

Answer: From 1978-1981, HCFA sponsored two voluntary second surgical opinion programs (SSOPs) in New York City and Detroit. These demonstrations showed that use of a voluntary SSOP for Medicare beneficiaries when cost-sharing for the second opinion is waived (i.e., 100 percent physician reimbursement) is low; less than 2 percent of beneficiaries recommended for an elective procedure obtained a second opinion through the formal program. The Medicare Part B program recognizes second opinions as a covered service. Data reported in Part B carrier claims records also indicates the very limited use of this service. Finally, HCFA supports a national public information campaign to promote the concept of getting second opinions. We estimate that this program receives approximately 1,000 inquiries per month nationally of which 40 percent are from persons over 65. Roughly one-half of these inquiries results in obtaining second opinions, and thus the effect of this program on reducing surgery is negligible.

It is accurate to say that voluntary SSOPs are of limited effectiveness in reducing surgery rates and thus controlling health care costs. While many business leaders have touted their effectiveness, to my knowledge, there have been limited independent evaluations of both voluntary and mandatory private sector second opinion programs of the effectiveness of these private sector second opinion programs or their impact on employee health. Moreover, in private programs, if the employee fails to get a second opinion, cost-sharing on the procedure increases to 20 percent versus no cost-sharing with the second opinion. Given the unique characteristics of the Medicare population, we would need to be sensitive to such consequencees in order to structure an equitable system beneficiary incentives/disincentives.

## MANDATORY SECOND OPINIONS

Question: It has been said that the PROs will engage in preadmission screening and this would serve as an alternative to mandatory second opinion programs. Will PROs pre-screen all elective surgical admissions or only a portion? What percentage do you estimate will not be covered, and why should we not mandate second opinions in those cases?

Answer: You are correct that PROs will perform preadmission review. However, such review is not necessarily envisioned as "an alternative to mandatory second opinion programs."

Peer Review Organization (PRO) contractors will generally be required to perform preadmission or preprocedure review on 5 elective procedures. The PRO will select these procedures from a listing, based on the 20 top cost and frequency DRGs (on a PRO-area-by-PRO-area basis), which has been provided by HCFA.

The PROs must perform preadmission or preprocedure review on more than 5 elective procedures where the PRO area average admission rate per 1000 Medicare beneficiaries is above the national average; where the PRO area admission rate is below the national average, the PRO may review fewer than 5 procedures.

We estimate that PRO preadmission and/or preprocedure review will examine an average of 5.9% of total Medicare admissions nationwide.

## RESEARCH AND EVALUATION REPORTS

Question: In recent years the budget under which HCFA reproduced commissioned reports, grant and contract reports, and reports on demonstration projects has declined. In order to permit Congressional oversight of your work, what arrangements have you established to see that these reports are available for Congressional review? Would you be willing to establish a routine policy of providing a single copy of these reports to the Congressional Research Service (if you are not doing this now) so that this information is available at minimal cost?

Answer: We currently produce a semi-annual report, Status Report: Research and Demonstrations in Health Care Financing, that provides a brief synopsis of each of the approximately 300 active intramural and extramural projects that the Office of Research and Demonstrations is conducting at any given time. This report is distributed to Congress as soon as it is printed, usually in April and October of each year. We also distribute copies of all of our other external publications to Congress as they are printed. These would include selected final reports (from projects that provide significant findings or are of high interest to the health community) which are produced as part of our Grants and Contracts Reports series.

However, the majority of our final reports from completed projects are sent to the National Technical Information Service (NTIS) which serves as a centralized repository. Users interested in the reports are provided ordering information and referred to NTIS to obtain copies in either paper or microfiche form.

To ensure availability to Congressional staffs of all the reports produced, we have worked out an agreement with the Chief, Health Section, at the Congressional Research Service to send one copy of every external publication we print as well as one copy of each final report we submit to NTIS to her attention for use as reference material. The Congressional Research Service staff will store the reports and ensure that they are made available for research purposes. I trust that this arrangement satisfactorily addresses your need for immediate access to information produced on the projects for which we have responsibility.

## KATIE BECKETT CASE

Question: Section 134 of TEFRA provided States the option of covering under Medicaid disabled children without regard to parental income if they meet five criteria. My question focuses upon one of those criteria. This condition requires that the disabled child "would be eligible for an SSI payment if in an institution." In Wisconsin an institutionalized SSI recipient would receive a $25 personal allowance payment unless that individual had other income (such as a minimal social security or railroad retirement payment) that exceeded $44.99. In those cases, the individual would remain SSI covered buy would not be entitled to a $25 payment. As the Department has interpreted Section 134 strictly, these cases have been refused covered under the 'Katie Beckett' rule. Could you review Departmental policy to determine whether these cases can be covered under the TEFRA provisions?

Answer: No. Section 1902(e)(3) of the Act, amended by section 134, requires that, to qualify for Medicaid at home, the disabled child be eligible to receive an SSI or State supplemental payment if he or she were residing in an institution. Generally, institutionalized individuals with monthly incomes over $44.99 have too much income to qualify for such a cash payment.

Question: Is a statutory change necessary to resolve this dilemma?

Answer: Yes. This could be accomplished by deleting the current requirement and, instead, by requiring that these individuals, if they were institutionalized, be able to qualify for Medicaid under Section 1902(a)(10) of the Act.

Question: Would you support such a change?

Answer: Yes. Although the statute and related Committee language are unclear as to the original intent of section 134, we believe the provision was meant to provide Medicaid to disabled children who would normally be barred from eligibility at home because of their parent's income.

Obviously, making the statutory change suggested above will make additional children eligible for Medicare at home. However, cost implications are unclear. To the extent that expanding eligbility for home-based care replaces more expensive Medicaid-funded care in an institution, making the suggested change will reduce Medicaid expenditures. We do not know the extent to which this is the case versus the extent to which Medicaid costs are increased due to the addition of newly eligible disabled children at home who are not and never have been at risk of institutionalization. We have no data on which to estimate how many such children might be added to the rolls. We believe the number would be very small as few disabled children have income separate from that of their parents. In either case, the advantages to disabled children of living at home with their families are so overwhelming that we would support changing the statute as suggested above.

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## QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

What steps is HCFA taking to evaluate the conditions needed to provide hospice care in rural communities and the ability of the December 16 rates to meet those conditions?

What steps is HCFA taking to evaluate the impact of the December 16 rates on the ability of Demonstration program to continue operation under these new rates?

What steps is HCFA taking to determine the impact of the December 16, 1983, rates on the number of clients living in rural areas? How many clients living in rural areas were served by the original Demonstration programs? How many are projected to have had the option to choose between hospice care and the more expensive hospitalization?

Answer: The Health Care Financing Administration (HCFA) is in process of designing and implementating an evaluation of the Medicare Hospice Benefit which will address many aspects of hospice care utilization, structure and processes. The HCFA will be addressing your questions regarding rural hospices and demonstrations program participants as a subset of those issues addressed in the proposed study of certified and non-certified hospice costs. A stratified random sample on non-certified hospices is proposed for selection for participation in a study of costs. Rural/Urban nature will be considered for inclusion as a stratification variable. Currently there are very few certified hospices which serve primarily rural areas. Although only four of the demonstration hospices have been certified, HCFA estimates that most will become certified before the end of the fiscal year.

The certified hospice and non-certified hospice cost data will be used in the study of the adequacy of the current reimbursement rates for different types of hospices and types of patients. Information regarding reasons for non-participation in the Medicare hospice program will be collected as part of the non-certified hospice cost study. The issue of continued hospice operation under the existing rate structure will be addressed under the evaluation. Should any certified hospice providers drop out, information regarding that decision will be collected.

Of the 25 demonstration hospice projects, only the Vermont hospice served a rural area. The Northern Vermont Respond, a consortium of 5 home health agency sponsored hospices, served 4879 terminial patients during the demonstration period.

## INTERMITTENT CARE

Question: I continue to be very concerned about HCFA's seeming lack of attention to the effective delivery of quality health care in rural areas. In February 1983, Vermont home health agencies told me of the added costs due to inconsistent and erratic interpretation of the definition of "intermittent care" when the HCFA intermediary considers Medicare reimbursement requests. Thirteen months later, I am still hearing of examples of the same problems.

It is well documented that "intermittent care" is an effective, appropriate and less expensive alternative to hospitalization in appropriate cases; therefore, I am puzzled and concerned that HCFA may actually be encouraging more costly health care. I have attached the two most recent examples brought to my attention by the Vermont Assembly of Home Health Agencies, Inc.

I would appreciate receiving answers to the following questions:

What steps has HCFA taken to standardize the definition of "intermittent care" for use by all intermediaries in all geographic areas?

Answer: We are concerned that Medicare coverage guidelines be administered as consistently as possible. While we need to maintain sufficient flexibility in our policy to permit the prudent application of medical judgment to individual cases, we also must provide sufficient training in medical review to prevent erratic interpretation of coverage rules. To this end, we have conducted and are continuing to schedule meetings between fiscal intermediaries and staff of the Health Care Financing Administration at the regional and central office level aimed at achieving a common understanding of Medicare coverage rules, including the intermittent care requirement.

Intermediaries have also been meeting with concerned providers to assure a shared understanding of these same rules. I met personally with representatives of the home health industry and concerned Congressional Committee staff to get first-hand input on the problems experienced with the intermittent care requirement and other home health issues. I asked the participants at the meeting for written comments and suggestions. I have received a large number of thoughtful comments over the past few months and intend to address these concerns to the degree possible.

Question: Why are cases in Vermont and New Hampshire being decided under a more restrictive definition than identical cases in other regions?

Answer: At the outset may I assure you that it is our goal that Medicare coverage policy be interpreted as consistently as possible on a national basis. As one might expect in so large a program, we do hear of situations in which the intermittent care definition or other coverage rules are being applied more strictly in one area than in another. Such reported variations are not confined to Vermont and New Hampshire but occur periodically throughout the country. Where we find the intermediary has clearly misunderstood policy guidelines, we require corrective action. In other cases we find that policy is well understood by the intermediary but that in the medical judgment of the fiscal intermediary the intermittent care requirement has not been satisfied. The appeals process seems the only appropriate remedy in such cases. I believe that some of the recent concern surrounding inconsistent enforcement of the intermittent care requirement is actually a product of our efforts to more consistently enforce coverage policy on a national basis. Providers not previously acquainted with various coverage requirements are being educated through our improved medical review procedures. However, as we continue to meet, communicate and train our intermediaries and providers, I believe the issue of inconsistent application of rules will abate.

## REVIEW SYSTEM FOR REIMBURSEMENT FOR INTERMITTENT CARE

Question: What steps has HCFA taken to introduce a rational, dependable review system into the intermediaries' administration and consideration of requests for reimbursement for "intermittent care?"

Answer: The Health Care Financing Administration (HCFA) has met with representatives of the home health industry, intermediaries and staff from HCFA regional offices in an attempt to both identify the problems with reimbursement for intermittent care and to reach uniformity in intermediary decisions.

To help in achieving uniformity in making medical necessity determinations, HCFA has developed a list of generic questions, which are to be answered by home health agencies when submitting claims.

## ENCOURAGING USE OF HOME CARE

Question: What steps has HCFA taken to encourage use of intermittent care whenever possible and when it is in the best interests of the patient?

Answer: The Health Care Financing Administration (HCFA) has funded over the past several years a number of demonstration projects aimed at testing the effectiveness of a coordinated home- and community-based long term care delivery system as an alternative to institutionalization. These demonstrations offered a broad range of home health and social services. In addition, HCFA granted to the projects waivers of various requirements that could be viewed as impediments to the use of home care services, such as the need for a prior hospitalization and the requirement that patients be homebound, in order to test the ability of these projects to provide more appropriate and cost effective care.

Initial finding from these projects have been mixed. In general, the early projects have demonstrated that, in the absence of a method to target services to a population at immediate risk of institutional care, expansion of home- and community-based long term care services would increase health care expenditures.

Evaluations of these projects are currently being conducted by two Federal contractors. Berkley Planning Associates is conducting a cross-cutting evaluation of several of the earlier projects. Mathematica Policy Research, Inc. is evaluating the effects of the National Long Term Care Channeling Demonstration. Findings from these evaluations will become available during 1984 and 1985. We expect that the evaluation findings will help us to more accurately identify persons for whom home care services are appropriate and cost effective.

## SOCIAL SECURITY ADMINISTRATION

## STATEMENT OF MARTHA A. McSTEEN, ACTING COMMISSIONER OF SOCIAL SECURITY

**ACCOMPANIED BY:**

**ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS**

**NELSON J. SABATINI, ASSOCIATE COMMISSIONER FOR MANAGEMENT, BUDGET, AND PERSONNEL**

**JO ANNE B. ROSS, ASSOCIATE COMMISSIONER FOR FAMILY ASSISTANCE**

**PHILLIP N. HAWKES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### INTRODUCTION OF ASSOCIATES

Senator WEICKER. Next we will hear the testimony on the budget request from the Social Security Administration, including the Office of Refugee Resettlement.

The witness is Martha McSteen, Acting Commissioner of Social Security. Your entire statement will be placed in the record, but you may wish to summarize it at this point.

Would you introduce your associates and proceed as you wish.

Mrs. MCSTEEN. Thank you very much, Mr. Chairman. I would like to introduce Nelson Sabatini on my right, Office of Management, Budget and Personnel for Social Security; Tony Itteilag, who you know from the Department, Jo Anne Ross, Associate Commissioner for Family Assistance.

Senator WEICKER. Mr. Hawkes is here?

Mrs. MCSTEEN. Mr. Hawkes is here, Mr. Chairman.

### OPENING REMARKS

Senator WEICKER. Why don't you go ahead.

Mrs. MCSTEEN. It's a pleasure to have an opportunity to represent Social Security and to spend a few moments telling you about the Social Security program.

We are presenting appropriations requests for $22.5 billion. As you know, that includes the payments to the Social Security trust funds, the Black Lung Program, as well as the SSI Program, the Assistance Payments Program, the Child Support Enforcement Program, the Refugee Program, and the limitation on administrative expenses account.

The old-age and survivors and disability insurance benefit payments are permanently appropriated and, therefore, are not a part of the request. We feel that the 1983 amendments did provide solvency to the trust funds that we were concerned about and that we now have stability in the programs in that respect.

There are several administrative initiatives that we have undertaken. Of course, No. 1 would be the Disability Program initiatives that we have undertaken to improve that entire process. We feel that administratively, we have done a number of things. For example, we now begin each continuing disability review with a face-to-face interview in the local SSA offices, and then this year, we are beginning the face-to-face hearings at the State reconsideration level. With the Secretary's initiatives last year, we began a top-to-bottom study of policies and procedures in the Disability Program, and I believe we have made significant strides in that respect.

In connection with service to the public, we are extremely concerned about the delivery of our services. We feel with the systems modernization plan that we have come a long way in being able to deliver those services timely and accurately to the beneficiary and the recipient as well as the taxpayer.

In addition, our last initiative that I will mention is debt prevention. For the past several years, we have made constant efforts to collect overpayments, and we know that the most important thing is to prevent those overpayments. We are working on a major project this year to prevent overpayments.

## PREPARED STATEMENTS

Thank you, Mr. Chairman. We are ready to be responsive to your questions.

[The statements follow:]

## STATEMENT OF MARTHA A. MCSTEEN

Mr. Chairman and members of the Committee, I am pleased to be here today to present the fiscal year 1985 appropriations requests of the Social Security Administration, the Office of Child Support Enforcement and the Office of Refugee Resettlement. These requests total $22.5 billion in budget authority.

### Summary of Budget Requests before the Committee

I would like to summarize the fiscal year 1985 requests before your Committee that require appropriations action.

-- $512.7 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to Federal funds.

-- $1.0 billion for Special Benefits to Disabled Coal Miners. These funds cover benefit payments and administrative expenses for that portion of the black lung program still administered by SSA.

-- $9.4 billion for the Supplemental Security Income program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.

-- $6.9 billion for the Assistance Payments program. This appropriation includes the Federal share of the benefit costs of the Aid to Families with Dependent Children program and funds for Federal policy direction, technical assistance and guidance in the administration of the AFDC program. Child Support Enforcement collections are included in this account as an offset to AFDC benefit payments.

-- $563.4 million for the Child Support Enforcement program. This appropriation provides funds for Federal, State and local administration of the program, the aim of which is to assure that absent parents meet their responsibilities to provide support for their children.

-- $359.5 million for Refugee and Entrant Assistance. This program reimburses States for the costs of providing direct cash and medical assistance to needy refugees and Cuban-Haitian entrants, as well as English language training, vocational training and other social services.

-- $3.7 billion for the Limitation on Administrative Expenses. This request provides resources needed to administer the old-age and survivors and disability insurance programs. It also includes funds to finance costs of certain administrative functions performed for the Medicare program by the Social Security Administration, and it includes administrative funds for the Supplemental Security Income program and several smaller activities. The trust funds are reimbursed for the administrative costs of the SSI and other non-trust funds programs through appropriations to other accounts. There is no fiscal year 1985 request for appropriations before the Committee for the Low Income Energy Assistance program at this time, because the authorizing legislation expires at the end of fiscal year 1984. However, the Administration's fiscal year 1985 budget, under proposed law, includes $1,875,000,000 for the program; and the Administration proposal is that the appropriations for the reauthorized program be derived from a Petroleum Overcharge Restitution Fund and supplemented by general revenues to the extent necessary.

## Social Security Financing

The President's fiscal year 1985 budget reflects implementation of the 1983 Social Security amendments, which have put the Old-Age and Survivors Insurance and Disability Insurance trust funds in a sound financial position. At the time the President's fiscal year 1984 budget was submitted, prior to enactment of the Social Security legislation, the estimated combined OASDI trust fund balance at the end of fiscal year 1985 was a deficit of $23.4 billion. As a result of enactment of the amendments, the estimated combined OASDI trust fund balance at the end of fiscal year 1985 shows a surplus of $35.6 billion. Funds to pay benefits from Old-Age and Survivors Insurance and Disability Insurance trust funds are permanently appropriated, and therefore are not part of the budget requests before this Committee.

## Agency Initiatives

Now I would like to report briefly on three of the Agency's key initiatives:

-- Disability Program: One of these initiatives is to alleviate the anxieties and misunderstandings of disability beneficiaries about what we call "CDR's"--continuing disability reviews.

You will recall that the Social Security Disability Amendments of 1980 contained a provision for improving program administration by requiring that SSA periodically review the Social Security disability rolls. You may remember that in a 1981 report GAO indicated that as many as 584,000 beneficiaries (about 18 percent on the rolls) did not meet the eligibility criteria. As SSA proceeded with the reviews, there was a strong, negative public reaction. Most beneficiaries, especially those who had been on the rolls for a number of years, had not expected to have their cases reviewed again. Terminated beneficiaries had to make tremendous psychological and economic adjustments. Few understood the very strict definition of disability in the Social Security Act. There were problems too with our procedures for conducting CDR's. For example, the CDR began without any personal contact between the Government and the beneficiary, and at the reconsideration level of appeal (the first appeal step) there was only a paper process in which the beneficiary never met the person who made the decision on his appeal.

The first administrative improvement we made was initiated in October 1982. From that date SSA has initiated all continuing disability reviews (CDR's) with a personal interview between the beneficiary and a Social Security employee, during which the purpose of the review and the rights and responsibilities of the disabled person are explained.

A second improvement in the CDR process is replacing the paper reconsideration procedure with a face-to-face evidentiary hearing. We are now implementing the new procedure, which resulted from a legislative change made last year--a change supported by the Administration. When we developed the budget request now before your Committee, we had assumed that Federal hearing officers would have to undertake the new face-to-face reconsideration hearing. Based on later information, we know now that in the vast majority of States there is a willingness to have State Disability Agency personnel do this job. Therefore, we would like to use most of the funds requested for Federal reconsideration hearings for hearings conducted by State agency personnel.

Other significant administrative reforms in the CDR process have been implemented as a result of initiatives announced by the Secretary of HHS in June 1983. These include the following:

o We reduced the number of beneficiaries to be reviewed every 3 years by revising our definition of permanent disability. Now roughly 40 percent, instead of about 30 percent, of disabled worker beneficiaries on the rolls are exempted from the 3-year periodic review.

- We suspended the review of mentally impaired beneficiaries with functional psychotic disorders until the criteria for reviewing these cases are revised.
- We initiated a top-to-bottom review of disability policies and procedures in consultation with appropriate experts and the States, and have increased our efforts to seek the advice of the medical community on the entire disability process.

-- Service to the Public--Systems Modernization: The primary administrative goal for SSA is to revitalize the way we provide service to the public. In spite of tremendous growth over the years in the complexity and breadth of the programs we administer, SSA has been able to improve service in a number of key areas. For example, in the last several years:

- We expanded the online data base so that local Social Security offices can provide immediate, automated benefit estimates for people age 60 and over, and
- We reduced the time for processing Social Security card applications from an average of 4 to 6 weeks to an average of 11 days.

Still, these isolated improvements were not enough, because our whole data processing system needed to be brought up to date. To solve our computer systems problems, we began a major systems modernization effort in February 1982. The first 18-month "survival" phase has been completed. One significant achievement so far has been elimination of tape files from many of our computer operations and their replacement with direct access disk storage.

During the last year we also upgraded other equipment and computer systems to provide improvements in service. We've used new equipment to eliminate the backlog of benefit recomputations for beneficiaries who had earnings after retirement and were due benefit increases. We are now working to improve our ability to process the 190 million reports of workers' earnings which we receive each year in the annual reporting process.

SSA's request for automatic data processing and telecommunications activities for fiscal year 1985 totals $210.2 million. This includes funds for the Systems Modernization Plan as well as ongoing systems costs and major telecommunication system procurement.

Over the next several years, our systems modernization work will allow further improvements in the ability of SSA employees in our field offices to deliver on-the-spot, accurate service. Beginning in 1985 we will pilot test what we refer to as our Field Office Systems Enhancement Project. The result of this project will be faster, more efficient, error-free service to the public. For example, we are planning a system that will enable our field office people, while interviewing a claimant, to enter information directly into our data processing system from the terminals at their desks, access any information in our central data records needed to process the claim and print out a completed paper copy of the application for the claimant to sign.

Another part of the systems overhaul is the improvement of SSA's management information system. We formed a project team to develop improvement plans in this area, and we are now proceeding to implement the team's recommendations.

The new technology, which is enabling us to serve the public better and more efficiently, will also enable us to gradually reduce our dependence on the labor intensive operating methods of the past. (About 25 percent of the OASI work that affects the amount of benefit payments is manually processed, but more than 50 percent of the payment errors occurs in this work.) The first effect of these improvements can be seen in our fiscal year 1985 request which reflects a relatively small reduction in SSA's total staffing needs to be accomplished through attrition. As implementation of the Systems Modernization Plan changes the methods we use to perform the work of the Agency, we recognize that some staffing imbalances may occur. Plans are being developed to minimize such imbalances by providing for future retraining and/or redeployment to insure that our workforce moves into the "computer age" along with our system. We have a loyal workforce dedicated to public service and we are looking forward to their continued support as we work together to improve our service to the public.

-- Debt Prevention: I would like to mention one other key area--that is, debt prevention. Over the past 2 years SSA has made great improvement in its debt management program. We have been striving to improve the accuracy of all benefit payments to reduce both overpayments and underpayments. We have markedly increased overpayment collections, and have progressed in setting up a modern accounts receivable system.

Collecting overpaid dollars, however, is not accomplished without cost, or without possible hardship to overpaid beneficiaries. We need to focus additional efforts on preventing as many debts as possible, and I have announced debt prevention as a major SSA initiative for this year.

The number one cause of overpayments is excess earnings under the annual earnings test. To reduce overpayments and underpayments based on estimated earnings, we need to get more accurate and up-to-date reports from our working beneficiaries. We are developing an action plan to accomplish this goal, including a public information campaign to increase public awareness of the need to keep SSA informed of work and earnings, and increased internal training to improve our ability to get more accurate estimates.

In concluding my statement, I want to thank the Chairman and all members of the Committee for your support of the Social Security Administration. You have been patient with us as we struggle to revitalize our automated systems. You have given us the funds to improve our administration of the disability program, and you have made a significant effort to help us to overcome our field space backlogs.

## PAYMENTS TO SOCIAL SECURITY TRUST FUNDS

The first appropriation request totals $512,722,000 and covers four Federal fund payments to the Social Security trust funds.

### Military Service Credits

The request before this committee for Military Service credits is for $357,000,000. This is the amount of estimated employer-employee OASDI payroll taxes for calendar year 1985 that would be paid on the deemed wage credits if the credits were treated as covered wages.

The Social Security Amendments of 1983 provided for a lump sum reimbursement to the trust funds for the present value of all future benefits payable due to granting free credits for military service before 1957. This lump sum, covering periods through September 30, 2015, is to be adjusted every fifth year beginning in 1985 for actual experience and relevant actuarial assumptions in the Social Security Trustees Report. The actual adjustment will not occur until the last quarter of calendar year 1985 and so this appropriation request does not include any adjustment to the lump sum determination for pre-1957 military service credits.

The 1983 amendments also require that the trust funds be paid on a taxes-due instead of a benefits-paid basis for post-1956 military service deemed wages beginning in calendar year 1984. The amendments authorized and appropriated a lump sum payment for post-1956 military service credits from 1957 through 1983 to reimburse the trust funds for taxes due as if the credits had been financed on this new basis.

## Special Payments to Certain Uninsured Persons

The second activity in this account is for payment of $104,978,000 to reimburse the old-age and survivors insurance trust fund for special benefits paid during FY 1983 to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These beneficiaries, a declining population, were not eligible for regular monthly Social Security benefits primarily because they retired before enactment of the Social Security Act or before their occupations were covered under Social Security. The Social Security Amendments of 1983 provided for equal payment of benefits to individuals who are married and who both qualify for special age 72 benefits. Prior to this amendment the wife received only half the amount that the husband received.

The Special Payments to Certain Uninsured Persons decreases by $19,536,000 from FY 1984. The population receiving special payments is a closed group of very aged persons which grows smaller each year. As of September 30, 1983, 53,000 persons were receiving benefits chargeable to the general funds under this provision as compared to 66,000 a year earlier.

## Reimbursement for Pension Reform Administrative Costs

The third activity is for payment of $744,000 to reimburse the old-age and survivors insurance trust fund for the Federal funds share of the cost of administering pension reform responsibilities assigned to the Social Security Administration under Public Law 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors. The FY 1985 estimate for pension reform administrative costs reflects a continuation of SSA's FY 1984 pension reform activities.

## Unnegotiated Checks

The fourth and final activity in this account is for payment of $50,000,000 to reimburse the trust funds for the value of benefit checks that remain uncashed after 6 months, plus interest. This is a new activity created by the Social Security Amendments of 1983.

Prior to the 1983 amendments, cash to cover unnegotiated Social Security checks remained in the general funds pending their being presented for payment. Thus, the trust funds never received credit for unnegotiated checks and lost interest income as well.

The 1983 amendments require the Treasury Department to establish a system by April 1, 1985 which identifies each unnegotiated Social Security check and automatically credits the trust funds each month for any not cashed after 6 months, plus interest. In the interim, these credits will be based upon joint HHS/Treasury estimates.

In FY 1983 Congress approved a $1,300,000,000 supplemental appropriation for unnegotiated checks. During FY 1983 HHS and Treasury analyzed the best available data and provisionally transferred $540,000,000 into the trust funds. This transfer will be finalized upon completion of a joint study of all Government checks outstanding at the close of FY 1983. This study is scheduled for completion in FY 1984 and, if necessary, additional sums appropriated in FY 1983 for prior year credits will be obligated and transferred. This study also will serve as the basis for computing actual monthly transfers for subsequent periods until Treasury modifies its system to automatically distinguish Social Security checks from all other Government checks.

## SPECIAL BENEFITS FOR DISABLED COAL MINERS

This appropriation request for Special Benefits for Disabled Coal Miners totals $1,024,131,000 and is financed from general revenues. It includes $1,015,000,000 for benefit payments and $9,131,000 for administrative costs. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that Agency.

### Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows of miners who were entitled to these benefits or whose deaths were due to this disease. Payments to miners or widows are increased for dependents--a spouse or child. Benefits also are payable to surviving children of miners and, in certain circumstances, to totally dependent surviving parents, brothers and sisters.

### Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners' benefits filed from December 30, 1969 through June 30, 1973 and claims for survivor benefits filed through December 31, 1973 or within

6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA must continue to pay benefits and maintain the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment of these claims, and thus budgets to reimburse SSA for this work.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come. At the mid-point of FY 1985, 304,000 miners, widows and dependents will be receiving monthly benefits paid by the Social Security Administration from this appropriation. This is a decrease of 22,000 from the 326,000 beneficiaries who will be receiving payments at the mid-point of FY 1984.

## Explanation of Change for FY 1985 Request

We estimate benefit payment obligations to be $1,015,000,000 in FY 1985--$30,000,000 less than in FY 1984. Because the President's budget assumes that the Federal civilian pay raise will be paid in January 1985 instead of October 1984, and the basic black lung benefit is tied to Federal pay scales, a black lung benefit increase of 3.5 percent in FY 1985 is budgeted to be payable in January 1985. The decrease in total benefits is due to a reduction of $49,000,000 for the lower number of black lung beneficiaries, a reduction of $4,000,000 for slightly lower average monthly payments for beneficiaries in current pay, and a partially offsetting increase of $23,000,000 due to the January 1985 benefit increase of 3.5 percent.

Our budget request of $9,131,000 for FY 1985 black lung administrative expenses is $101,000 lower than the level estimated for FY 1984. This is caused by a reduction in ongoing workloads based on the decline in the number of beneficiaries on the roll.

## Proposed Transfer

Due to lower FY 1984 benefit costs than previously anticipated, the President's FY 1985 budget proposes to transfer $10,000,000 in unobligated FY 1984 budget authority from the Special Benefits for Disabled Coal Miner's appropriation to the supplemental security income (SSI) program appropriation to fund a portion of the January 1984 civilian pay raise cost for that account.

## Advance Appropriation

The budget request includes an advance appropriation of $270,000,000 for the first quarter of FY 1986. This request insures that benefit payments will be made to individuals in the event of a temporary delay in enactment of 1986 appropriations.

## SUPPLEMENTAL SECURITY INCOME

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for FY 1985 is $9,383,076,000. This includes $8,420,786,000 for Federal benefits to aged, blind and disabled recipients, including $36,786,000 to be drawn down for FY 1984 needs; $5,000,000 for beneficiary rehabiliatation services; $936,175,000 for payments to the trust funds for administrative costs; and $21,115,000 for reimbursing States for incorrect State supplementary payments made as a result of Federal errors. The appropriation request for FY 1985 anticipates savings of $16,000,000 from new legislation.

## Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

The average monthly number of SSI recipients of Federal benefits are projected to increase from 3,667,000 in FY 1984 to 3,714,000 in FY 1985, an increase of 47,000. This increase is due to projected growth in the number of blind and disabled SSI recipients partially offset by a slight decrease in the projected number of aged SSI recipients.

The FY 1985 request for Federal benefit payments, excluding funds drawn down for FY 1984, is $8,384,000,000 or $964,000,000 higher than the FY 1984 level. The major cause of this year-to-year increase is the accelerated check provision which results in 11 months of benefit payments in FY 1984 in contrast to 12 months of benefit payments in FY 1985. After adjusting for the difference in the number of payments and proposed legislation, the FY 1985 request represents a comparable increase of $350,000,000 for Federal benefit payments. This increase is needed to fund:

-- The 4.3 percent cost of living increase projected for January 1, 1985 and
-- The projected increase in the number of blind and disabled recipients.

The budget anticipates savings of $16 million in FY 1985 from proposed legislation. The two proposals will:

-- Authorize the cross-program recovery of overpayments made to an individual under either OASDI or SSI from current benefits payable to the same individual from the other program. The estimated savings from this proposal are $11 million.
-- Expand the authority provided by the Disability Amendments of 1980 to allow "windfall" SSI benefits to be offset when OASDI benefits for the same period already were paid.

Whenever an SSI recipient becomes eligible for OASDI benefits which are retroactive to an earlier period, the law currently permits SSA to deduct from the retroactive check the amount of SSI benefits which would have not been paid had Title II benefits been paid promptly. However, there is no similar adjustment where the SSI check is issued after the retroactive OASDI payments. The proposed change would eliminate these "windfall" SSI benefits by adjusting the retroactive SSI payments to equal the amount that would have been paid had both SSI and OASDI benefits been paid promptly. Estimated savings from this proposal is $5 million.

## Beneficiary Rehabilitation Services

As a result of the Omnibus Budget Reconsiliation Act of 1981, SSA provides funds only to reimburse vocational rehabilitation agencies for costs incurred in successfully rehabilitating SSI recipients. Based on this change in law, we estimate that $3,000,000 will be required for vocational rehabilitation in FY 1985. In addition, we are requesting $2,000,000 for the referral and monitoring of SSI recipients who are drug addicts and alcoholics.

## Payments to the Trust Funds for Administrative Costs

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system which has been audited by the General Accounting Office to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1985 request for this activity is $936,175,000.

## Federal Fiscal Liability

The Social Security Administration administers supplemental payments for 26 States and the District of Columbia. Agreements with the States governing Federal administration of these State supplementary payments provide for Federal fiscal liability (FFL) for payment errors in excess of a 4 percent tolerance.

SSA's FFL estimates are largely dependent on two factors: FFL error rates and the resolution of negotiations with the States over disputed periods. This budget assumes that all outstanding FFL through September 1983 will be settled in FY 1984. We are requesting $21,115,000 for this activity in FY 1985.

## Advance Appropriation

The budget request includes an advance appropriation of $2,345,769,000 for the first quarter of FY 1986. This request insures that benefit payments will be made to individuals in the event of a temporary delay in enactment of 1986 appropriations.

## ASSISTANCE PAYMENTS

This appropriation finances the Assistance Payments program which provides funds through grants to States and local governments for diverse activities related to public assistance to the needy. Although the Social Security Administration is responsible for the programs covered by this appropriation, no trust fund money is used for assistance payments purposes. For fiscal year 1985 the Assistance Payments request, which includes $633,000,000 in assumed savings from proposed legislation, is $6,944,025,000. The total appropriation for FY 1985 is the sum of the regular appropriation requested at this time ($4,871,025,000) and the advance appropriation for the first quarter of FY 1985 previously enacted ($2,073,000,000). The total request includes $6.9 billion for maintenance assistance, which includes Aid to Families with Dependent Children and related programs; $2.58 million for research and evaluation; and $35.0 million for Federal administrative expenses.

At this time, we are also requesting an advance appropriation for $1,812,840,000, which includes assumed savings from proposed legislation, to fund first quarter FY 1986 grants. This advance appropriation is the mechanism, which replaced "borrowing" authority, for providing funds in the current year for issuing first quarter advance grants for the next fiscal year. The mechanism protects the States from gaps in funding and enables them to plan in advance for first quarter operations.

Before we get into the reasons for the year-to-year change in our appropriation request, I'd like to make two general points:

--The FY 1985 appropriation request is about $1.1 billion less than the FY 1984 appropriation.

--The FY 1985 appropriation request, however, is about $235 million higher than our current estimates for FY 1984 when adjustments are made to the 1985 estimates for the impact of proposed legislation ($0.6 billion) and to the FY 1984 and FY 1985 appropriations for financing adjustments. The financing adjustments include FY 1984 amounts used to fund costs incurred in FY 1983 ($0.2 billion), FY 1984 amounts used to funds costs anticipated in FY 1985 ($0.2 billion) and FY 1984 funds transferred to the Department of Agriculture ($0.1 billion).

The following portions of this statement address in more detail the FY 1985 request, including the impact of legislation proposed for enactment in FY 1985, for the maintenance assistance, research and evaluation, and federal administration activities.

## Maintenance Assistance

The fiscal year 1985 request for the Federal share for the maintenance assistance activities is $7,106,434,000. The request includes:

--$5,963,000,000 for Aid to Families with Dependent Children (including a reduction for offsetting child support collections of $440,000,000).

--$14,014,000 for assistance to aged, blind and disabled adults in Puerto Rico, Guam and the Virgin Islands; the Supplemental Security Income program does not cover these jurisdictions.

--$56,100,000 for emergency assistance to needy families with dependent children.

--$1,066,083,000 for State and local administrative and training costs related to the maintenance assistance programs.

--$5,717,000 for administration and training costs in Puerto Rico, Guam and the Virgin Islands.

--$1,520,000 for assistance to repatriated U.S. Nationals returning from foreign countries who have been certified by the Department of State as destitute or ill.

The FY 1985 request for these maintenance assistance activities is $395,365,000 lower than the FY 1984 level for the same activities. This decrease is the net result of several factors of decrease and increase primarily in the AFDC and State and local administration and training costs activities. Significant decreases in the Federal share of program costs result from the following factors:

--A decrease of $768 million from the FY 1984 level as a result of savings from legislation proposed for enactment in FY 1985 which would strengthen AFDC work requirements and target AFDC benefits more fairly.

--Savings of $23 million are projected from Child Support Enforcement legislative proposals which would increase collections on behalf of AFDC families as well as emphasize services to nonwelfare families, thereby helping them to stay off the welfare rolls.

--Increased savings of $25 million in Child Support Enforcement collections resulting from increases in the caseload.

Significant increases in AFDC and State and local administration and training, are:

--AFDC increases $75 million as a result of economic and demographic factors including: an increase in average benefits, due to both inflation and increases in State standards of need; an increase in the number of families headed by females, the major source for the AFDC caseload; and an offsetting decrease in the unemployment rate.

--State and local administration and training increases $198 million primarily as a result of projected costs associated with the Administration's legislative proposal to require all applicants to participate in job search and all employable recipients to participate in work programs. These costs are more than offset by the savings of $329,000,000 in AFDC benefits.

$40 million of the estimated increase in State and local administration results from projected increases in wages and prices.

## Research and Evaluation

We are requesting $2,575,000 for research and evaluation grants and contracts under sections 1110 and 1115 of the Social Security Act, a reduction of $425,000 over the FY 1984 level. The aim of these projects is to improve the management of the AFDC program and to assess policies which promote work experience for recipients and thus reduce welfare dependency. Some of the projects planned include demonstration of techniques to improve the effectiveness of Community Work Experience programs, evaluation of grant diversion and demonstration of fraud and error reduction methods. Although most of the money is for research and demonstration projects related to the AFDC program, some of the funds are used for Social Security and SSI extramural research grants and contracts.

## Federal Administrative Expenses

The FY 1985 request includes $35,016,000 for Federal administrative expenses; a decrease of $1,703,000 over the FY 1984 level, and 714 full-time permanent positions, a decrease of 40 from FY 1984. An increase of $952,000 for mandatory costs such as the costs of the full-year effect of the January 1983 pay raise, within-grade raises and promotions, rent, and utilities is offset by a decrease resulting from management initiatives to reduce staff and increase productivity. The FY 1985 request provides the resources necessary to continue the efforts, at the FY 1984 level, to implement and evaluate the provisions of the Omnibus Budget Reconciliation Act of 1981 and the Tax Equity and Fiscal Responsibility Act of 1982.

## CHILD SUPPORT ENFORCEMENT

The Child Support Enforcement appropriation provides funds through grants to States to enable them to assist families by locating absent parents, establishing paternity, obtaining child support orders and enforcing the support obligations owed by absent parents to their children. The aim of the program is to help families maintain their financial independence and stay off public assistance by assuring that absent parents meet their responsibility to support their children. The FY 1985 budget request is for $425,411,000 including $19,000,000 savings from proposed legislation. This is in addition to the $138,000,000 which Congress provided as an advance appropriation to fund first quarter State and local administrative grants. Therefore, the total FY 1985 appropriation is $563,411,000. This includes $545,000,000 for the Federal share of State and local administrative costs, $17,911,000 for Federal administrative expenses and $500,000 for research and evaluation.

At this time we also are requesting an advance appropriation of $160,000,000 to fund first quarter FY 1986 grants. The advance appropriation will provide funds in FY 1985 for issuing advance grants for the first quarter of FY 1986. Such a procedure enables States to continue program operations without interruption and to plan in advance.

The appropriation request for FY 1985 reflects projected savings of $19,000,000 from legislation proposed for enactment in FY 1984. The proposed legislation reflected in the budget is H.R. 4325 as passed by the House of Representatives November 16, 1983, with some modifications. H.R. 4325 was unanimously approved by the House and is awaiting Senate action. The legislation reflected in the budget proposes to reform the child support enforcement program in a number of important ways. First, it reaffirms our commitment to provide child support enforcement services to welfare and nonwelfare families alike by providing States, for the first time, with a monetary incentive to obtain child support for nonwelfare families. Second, proposed reforms would change program financing to focus more on results and to encourage more cost effective programs. As a part of the heightened emphasis on relating financing to performance, the proposed legislation would reduce the Federal matching rate from 70 percent to 65 percent and provide for application fees as well as fees to encourage timely support payments. Third, the proposals would also increase child support collections by requiring states to adopt proven enforcement techniques. These include mandatory wage withholding when payments are delinquent, State income tax refund offsets for delinquent payments, and use of quasi-judicial or administrative procedures to establish and enforce obligations.

## State and Local Administrative Costs

The FY 1985 request for the Federal share of State and local administrative expenditures is $545,000,000 which is $6,485,000 higher than anticipated program costs for FY 1984. This small increase is contingent on Congress enacting the previously mentioned child support legislation package, which is projected to produce savings of $19,000,000 in FY 1985. The increase in expenditures over FY 1984 is accounted for by increased caseloads and by States claiming higher levels of expenditures for reimbursement. The increase, however, is offset by $48,000,000 of savings in the AFDC program which are reflected in the AFDC appropriation. These savings are attributable to higher levels of child support collections and to lower AFDC caseloads as a result of families receiving child support rather than public assistance.

## Research and Evaluation

We are requesting $500,000 for research and evaluation grants and contracts under section 1110 of the Social Security Act, $50,000 more than last year. These funds will be used to study ways to assess the ability of absent parents to pay child support, and for other purposes.

## Federal Administrative Expenses

The FY 1985 request includes $17,911,000 and 241 permanent positions for Federal administration. This represents a decrease of $4,289,000 over the FY 1984 appropriation level. The request includes a transfer of the OCSE audit function to the Office of the Inspector General in the Department of Health and Human Services. On a comparable basis, however, the FY 1985 request is above the FY 1984 level by $619,000. The extra funds are needed to cover the costs of the full-year effect of the January 1984 pay increases increased telecommunications costs, within-grade raises, promotions, Social Security contributions for new Federal employees and other mandatory increases. During FY 1985, OCSE will continue its strategy of providing direct assistance to jurisdictions and especially urban areas where collection performance can be improved. Dramatic results have been achieved in some areas, and we expect continued success.

The Office of Child Support Enforcement also performs reimbursable work for States. This reimbursable work requires 2 workyears and has an estimated cost of $96,000. This activity is authorized by the Federal Parent Locator Service to locate parents with custody of a child in violation of a court order.

## LOW INCOME HOME ENERGY ASSISTANCE

The Low Income Home Energy Assistance Program provides funds through grants to States and Indian tribes to enable them to provide assistance to low income households in meeting the costs of home energy. There is no pending request before the Committee because there is no current legislative authorization for FY 1985. The program's authorization under the Low Income Home Energy Assistance Act of 1981, contained in title XXVI of the Omnibus Budget Reconciliation Act of 1981, expires at the end of FY 1984. The Administration's budget request includes $1,875,000,000 for FY 1985 under proposed legislation. The appropriations will come from a proposed fund which will be designated the "Petroleum Overcharge Restitution Fund." The $1,875,000,000 request will include $2,103,000 for Federal administrative expenses.

### Petroleum Overcharge Restitution Fund

The Administration has proposed that the appropriations for the Low Income Home Energy Assistance Program be derived from "The Petroleum Overcharge Restitution Fund." Funds recovered from settlement of suits stemming from petroleum pricing violations under the Emergency Petroleum Allocation Act of 1973 would be deposited in the fund to the extent that efforts to identify and repay the overcharged customers are unsuccessful. This fund will therefore allow Congress to determine the distribution of these overcharge funds in cases where the overcharged customers cannot be identified or repaid. Under the proposed legislation, general revenues would supplement this fund to the extent necessary to insure funding of the program at the authorized level of $1,875,000,000.

## Program Grants

We will request $1,872,897,000 in FY 1985 to provide grants to States and Indian tribes to aid low income families through payments to eligible households and energy suppliers. This assistance is primarily for heating but may be used for cooling costs or low cost weatherization. The FY 1985 request will allow continuation of program activities at the current authorization level.

## Federal Administration

The FY 1985 request will include $2,103,000 for funds to enable the Social Security Administration to administer the energy block grants for States and Indian tribes. The FY 1985 request is for 40 permanent authorized positions. Administrative activities include reviewing State and Indian tribe applications and amendments, issuing grants, compliance and monitoring reviews, financial management functions, and preparing the annual report to Congress. The $2,103,000 represents a $193,000 decrease from the FY 1984 level which reflects reduced Federal staffing for overhead and technical assistance and savings from other management initiatives.

## LIMITATION ON ADMINISTRATIVE EXPENSES

The Limitation on Administrative Expenses is a request for authority to spend up to $3,724,515,000 in FY 1985 from the trust funds for administrative expenses of the Social Security Administration. From this account we pay for administration of the old-age and survivors and disability insurance programs, Medicare work performed by SSA, and the construction needs of the Social

Security trust fund programs. In addition, because for reasons of economy and efficiency SSA has integrated administration of both trust fund and some nontrust fund programs, the law authorizes payment of certain nontrust fund administrative expenses from this account, with full reimbursement from general funds. The nontrust fund work handled in this way includes work relating to the Supplemental Security Income Program, work associated with the Pension Reform Act of 1974, and the portion of annual wage reporting work done by SSA for the benefit of the Internal Revenue Service.

Of the new budget authority requested:

--$1.2 billion is for administering the old-age and survivors insurance program,

--$1.3 billion is for the disability insurance program,

--$133.2 million is for SSA's Medicare support functions,

--$936.2 million is for administering the SSI program,

--$78.1 million is for processing annual reports of earnings,

--$0.7 million is for pension reform responsibilities,

--Included in these activities is an estimated $210.2 million for automatic data processing and telecommunications activities,

--Another $33.3 million is for SSA's purchase contract payments and

--$50.0 million is for the contingency reserve, which provides funds to SSA only if workloads, automation projects and certain other specified costs exceed the budget estimates.

## Budget Emphases for FY 1984 and FY 1985

SSA's administrative budget request reflects four general areas of emphasis in fiscal years 1984 and 1985. I've already discussed three of these in my general opening statement. I will just touch on them briefly here.

1. Automatic Data Processing and Telecommunications

The FY 1985 request for new budget authority is $210.2 million, an increase of about $10 million over the FY 1984 comparable level. This amount will fund SSA's continuing progress towards modernizing its systems hardware and software as well as the Agency's ongoing systems costs. Included in this amount is $18.1 million for major telephone systems procurement. Flexibility in implementation of the Systems Modernization Plan has been helped by special appropriations language first approved by your Committee for FY 1982 and requested again for FY 1985. This language allows SSA to use appropriations for ADP and telecommunications until they are expended.

2. Implementation of the Social Security Amendments of 1983

One of SSA's most significant administrative undertakings in FY 1984 and FY 1985 will be the continued implementation of the Social Security Amendments of 1983. The budget request includes our current estimate of $102.5 million and 2,646 workyears for FY 1984 and $101.2 million and 2,421 workyears for FY 1985 to implement the Amendments. The major amendments that require administrative resources in FY 1984 and FY 1985 are:

- The increase in the supplemental security income (SSI) payment standard (effective July 1983) and the provision requiring special notification to aged Social Security beneficiaries of the availability of SSI (to be completed by July 1984). We expect that these provisions will increase SSI claims and post-entitlement workloads as new SSI recipients are added to the rolls. The majority of the claims workloads will be completed by the end of FY 1984.

- The taxation-of-benefits provision. Under this provision (effective for taxes paid for calendar year 1984), one-half of Social Security benefits received by taxpayers whose income exceed $25,000 for a single taxpayer (or $32,000 for married taxpayers, filing jointly) have to be included in taxable income. Beginning in January 1985, SSA must provide annual statements of benefits paid to all beneficiaries. A substantial portion of the resources requested in FY 1985 are for additional inquiry workloads in SSA field offices.

The budget assumes SSA can accomplish this additional work in FY 1984 without additional resources, primarily because of productivity improvements from systems modernization and procedural changes. The contingency reserve for this account is available to finance added workloads should our estimates prove to be too low.

3. Debt Management

As a result of SSA's efforts, collections of debt from all programs rose from $635 million in FY 1981 to more than $1.3 billion in FY 1983.

SSA has three debt management goals: (1) to prevent new overpayments, (2) to detect and collect current debts promptly, and (3) to recover old debts which remain collectible. In FY 1985 SSA expects to use about $172 million and 6,300 workyears in the OASDI and SSI programs to collect more than $1.4 billion--a net savings of over $1.2 billion. The administrative resources needed for debt collection in 1985 are projected to decline by $30 million and 1,200 workyears, as compared to FY 1984, as the result of improved debt management practices and the completion of non-recurring work in 1984. For example, savings are expected from consolidation and automation of billing, and telephone follow-up and remittance operations.

The improved debt management practices are designed to raise the public's confidence in the quality of program administration. At the same time, in fairness to the beneficiary, SSA will continue to recognize the overpaid individual's rights to due process.

## 4. Disability Program Administration

SSA's budget reflects the Administration's plan to provide fair treatment of individual beneficiaries and claimants while insuring the integrity of the disability rolls. The total number of continuing disability reviews (CDR's) in the budget is 472,000 for FY 1984 and 430,000 for FY 1985. This includes 312,000 CDR's in FY 1984 and 274,000 in FY 1985 under the periodic review requirements of the Social Security Disability Amendments of 1980.

The budget request includes $706.1 million for the Disability State agencies, an increase of $21.9 million over the $684.2 million budgeted for FY 1984. Funds for the State agencies account for about 19 percent of the total amount for the Limitation account. For the Disability State agency budget we propose an increase in the rate of purchase of consultative examinations from about 42 percent in 1983 to about 47 percent in 1985. The continuing disability review process has contributed to this increase.

As indicated earlier, when we developed the budget request before your Committee, we had assumed that Federal hearing officers would have to undertake the new face-to-face reconsideration. To date, the majority of States, about 45, have elected to conduct the disability hearings themselves. We would like to adjust the distribution of Federal and State dollars as needed, based on final State elections.

I would like to say something about the requests for hearings before Administrative Law Judges (ALJ's) in SSA. Our pending workload in this area is now about 158,000. However, ALJ productivity has increased, and the new face-to-face reconsideration hearing procedure will benefit the entire appeals process by resolving more cases at the reconsideration level instead of in a hearing before an ALJ.

## Workloads

SSA has a workload-based administrative budget. Some examples of principal workloads for FY 1985 are to:

--process over 3.7 million claims from retired workers, dependents and survivors; nearly 1.4 million claims from disabled workers, dependents and survivors; and about 1.1 million SSI claims.

--keep the beneficiary rolls current for 36.9 million persons under the Social Security cash benefit programs and for 4.0 million SSI recipients.

--complete 3.0 million redeterminations for SSI eligibility and payment amount.

--process more than 452 thousand hearings from claimants who are appealing decisions concerning their eligibility and benefits, primarily in the disability and SSI programs.

--post 209 million annual wage report items.

## Workyears and Positions

For this appropriation, SSA is requesting 84,033 workyears for FY 1985, a decrease of 2,845 workyears from FY 1984. This workyear decrease results from several factors. First, we are implementing additional procedural changes and systems improvements that will improve productivity of our staff and enhance service to beneficiaries. Those improvements include the following:

- o automation of benefit computations for the proration of the first month's SSI benefits and the offset of retroactive OASI benefits for SSI benefits received during the same period.
- o automation of SSI overpayment notices.
- o expansion of the claims automated processing system to include certain cases formerly excluded from automated processing and handled manually.

Second, we have some workload decreases, due in part to completion of non-recurring work in FY 1984. The FY 1985 request assumes that there will be:

- lower school attendance workloads as a result of the Omnibus Budget Reconciliation Act of 1981,
- completion of a non-recurring backlog of high priority post-entitlement workloads in FY 1984, and
- fewer resources needed in 1985 than in 1984 to implement the supplemental security income provisions of the Social Security Amendments of 1983.

For the Limitation account we are asking for 76,981 full-time permanent authorized positions in FY 1985. This is about 1,400 positions lower than the FY 1984 level. We also are projecting a decrease of about 700 workyears in overtime in 1985.

## Construction

The FY 1985 request includes $33.3 million in new budget authority for annual purchase contract payments on buildings previously constructed. No new budget authority is requested for headquarters and district office projects, since budget authority from prior years is available to meet the requirements of projects currently underway or planned. Since annual purchase contract payments can be met from the annual appropriation, the new budget authority has been requested without a no-year earmark.

## STATEMENT OF PHILLIP N. HAWKES

Mr. Chairman, members of the subcommittee, I appreciate the opportunity to discuss the refugee and entrant assistance programs of the Department of Health and Human Services, and the budget that we are proposing for FY 1985.

Title IV of Immigration and Nationality Act and Section 501 of the Refugee Education Assistance Act of 1980 (Public Law 96-422) authorize a comprehensive program of cash and medical assistance and social services for refugees and Cuban and Haitian entrants. By the end of fiscal year 1983, 49 States, the District of Columbia and Guam had approved State plans for refugee resettlement. In addition, 33 States and jurisdictions currently provide assistance and services on behalf of Cuban and Haitian entrants.

The FY 1985 budget request for refugee and entrant assistance is $359,512,000. This request is for a single appropriation for the Refugee Assistance and Cuban/Haitian Entrant Programs and is premised on Congressional reauthorization of the Refugee Act of 1980 which expired at the end of FY 1983.

The FY 1985 budget request for Refugee and Entrant domestic assistance represents a decrease of nearly $155,000,000 from the $514,461,000 appropriated under the Continuing Resolution for FY 1984. This reduction reflects an anticipated decline of 74,000 in the number of refugees/entrants who will be eligible for cash and medical assistance in FY 1985. There will also be a parallel reduction in the need for targeted assistance and education assistance as the eligible refugee/entrant population continues to decline.

The Department supports a policy that would make voluntary resettlement agencies responsible for the basic needs of refugees during their first 90 days in this country. For this purpose, $15 million from the total Refugee budget would be allocated to the State Department for distribution to voluntary agencies. This initiative is intended to clarify responsibilities and relationships between Voluntary agencies and welfare agencies and will increase the opportunities for refugees to establish early financial independence and otherwise avoid unnecessary and often long-term dependence on welfare programs.

There are six activities proposed under the refugee and entrant programs in FY 1985: State Administered Programs, Targeted Assistance, Education Assistance for Children, Preventive Health, Voluntary Agency Programs and Federal Administration. These may be summarized briefly as follows:

1) State Administered Programs. We are requesting $307,610,000 under this activity in FY 1985 which will provide Federal funds to reimburse the State's share of cash and medical assistance provided to refugee/entrants eligible for and receiving benefits under the programs for Aid to Families with Dependent Children (AFDC), Medicaid (Title XIX of the Social Security

Act) and Supplemental Security Income (SSI). Federal funds will be made available for such costs during the 36 month period after the individual's arrival in this country.

In FY 1985, 100% Federal funding will continue to be made available for non-AFDC and non-medicaid eligible refugees/entrants for cash and medical assistance provided to refugees/entrants, who meet State income tests, for the first 18 months from the date of arrival in this country. For the second 18 months, refugee/entrants eligible for State or local General Assistance programs will receive cash and medical assistance on the same basis as non-refugees with full Federal reimbursement.

The State Administered Program activity will also make funds available for refugee/entrant social services programs and for services for unaccompanied minors and related administrative costs under the State Administered programs.

2) Targeted Assistance. We are requesting $19,390,000 in Federal targeted assistance to assist refugee/entrant populations in those areas where supplementation of available resources remains necessary due to high concentrations of refugee and entrants. This activity is being funded at $62 million below the FY 1984 level on the basis of decreased actual refugee admissions for the third consecutive year and ORR's initiatives in refugee placement policies.

3) Education Assistance for Children. This activity, for which we are requesting $12,976,000 in FY 1985, is a program for education assistance for children to relieve school districts of the initial cost of meeting the special needs of refugee children. This activity is being funded in FY 1985 at $3.6 million below the FY 1984 level on the basis of continued reduced refugee admissions and that capacity has been established to meet the special educational needs of refugee/entrant children.

4) Preventive Health. We are requesting $8,891,000 million in FY 1985 to support two basic functions related to the health care for refugees.

The first is monitoring the adequacy of medical screening and assuring appropriate follow-up and treatment of refugees with diseases of public health concern. This work will be conducted by Centers for Disease Control (CDC) personnel stationed overseas and at ports of entry. They will work to assure the continued high quality of medical screening and disease surveillance overseas and the inspection and state notification procedures at ports of entry. They will also continue to operate a computer system for refugee medical records and a tracking and notification system for refugees with class A/B tuberculosis, class B venereal disease and class B leprosy.

The second function covers a modest grant program administered by CDC to support State and local health agencies which conduct health assessments and immediate follow-up care for a variety of conditions including skin infections, intestinal parasites, malnutrition, and anemia. In addition this activity will provide support to State and local health departments for follow-up and preventive treatment of refugees found to have tuberculous infection.

The FY 1985 budget request for preventive health provides for a $4.5 million increase, over the FY 1984 level, to enhance the Department's efforts in the refugee health screening and notification program and in the health assessment grant program.

5) Voluntary Agency Programs. This activity provides matching funds on a dollar-for-dollar basis, up to a specified maximum of $1,000 per refugee, to voluntary agencies for services in resettling refugees. The voluntary agency program is not intended as a supplemental program to State Domestic Assistance, but is an alternative program to provide national voluntary resettlement agencies with matching Federal funds for resettlement assistance and services primarily for Soviet refugees. The principal objective is to enable the refugees to become self-supporting and independent members of American society. A wide range of activities is covered including training, recertification in the United States for professionals trained abroad, critical social services and maintenance assistance.

Funding is provided for this activity in lieu of regular State administered cash and medical assistance and social services. For FY 1985, as in FY 1984, we are requesting $4 million for this program activity.

6) Federal Administration. The Office of Refugee Resettlement (ORR) was established by the Refugee Act of 1980 to be responsible for the management of the domestic refugee resettlement program. We are requesting $6,645,000 in FY 1985 for ORR to administer the annual appropriation for refugee and entrant assistance, to monitor the recipients of Federal grants under the Refugee Resettlement Program and the Cuban/Haitian Entrant Program, both fiscally and programmatically, and to continue and develop as well new national initiatives (such as planned secondary resettlement, english language training and employment standards) in response to the problems of domestic resettlement.

I wish to thank you for the opportunity to address this subcommittee. I am prepared to respond to questions at this time.

Budget Authority by Activity
Refugee and Entrant Assistance
( $ in thousands )

| Activity | 1983 Actual | 1984 Request | 1984 Appropriation | 1984 Revised Request | 1985 Estimate |
|---|---|---|---|---|---|
| State Administered Programs | | | | | |
| Cash Assistance | $226,711 * | $224,040 ** | $200,128 | $200,128 | $147,645 |
| Medical Assistance | 120,019 * | 102,814 ** | 110,437 | 110,437 | 79,865 |
| State Administration | 52,010 * | 30,296 ** | 46,585 | 46,585 | 33,900 |
| Social Services | 71,700 | 57,536 | 44,400 | 44,400 | 46,200 |
| Total, State Administered Prog. | 470,440 | 414,686 | 401,550 | 401,550 | 307,610 |
| Targeted Assistance | 81,500 | 35,000 | 81,500 | 81,500 | 19,390 |
| Education Assistance for Children | 16,600 | 16,600 | 16,600 | 16,600 | 12,976 |
| Preventive Health | 6,049 | 8,450 | 4,400 | 4,400 | 8,891 |
| Voluntary Agency Programs | 4,000 | 4,000 | 4,000 | 4,000 | 4,000 |
| Federal Administration | 6,411 | 6,592 | 6,411 | 6,515 *** | 6,645 |
| Total, Refugee and Entrant Assistance | $585,000 | $485,328 | $514,461 | $514,565 | $359,512 |

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* Includes the amounts for Cuban/Haitian Entrants assistance, which was shown as a separate activity in FY 1983.

** Includes the amounts for Cuban/Haitian Entrants assistance, which was shown as a separate activity in the original FY 1984 budget request.

*** The FY 1984 Continuing Resolution (Public Law 98-151) level is $6,411 (000) for this activity. The increase of $104 (000) in the current estimate is for the Federal pay raise effective January 1984.

## NEWSWEEK REPORT ON SOCIAL SECURITY

Senator WEICKER. The April 2 edition of Newsweek says that Secretary of the Treasury Regan, who is Chairman of your Board of Trustees, wanted the trustees' annual report, due out this week, to reflect his belief that the Social Security Administration is underestimating the life spans of retirees, understating the percentage of Americans who retire at 62, and overestimating the health of the economy. The Newsweek story indicates that Secretary Regan thinks you will run short of funds again in the 1980's.

Is the Newsweek report accurate?

Mrs. MCSTEEN. Not to my knowledge. I am not aware that Secretary Regan made that precise statement. I am aware of the fact that our staffs have been working very closely. The trustees' reports have not been issued, as you know, and the Secretaries of Treasury, Labor and HHS are discussing the major issues. The trust fund safety margins in the near term we knew would be thin and that was known at the time of the 1983 amendments and it was part of the plan. We hope that the trustees' reports will resolve the remaining issues and that they will be issued in a few days.

Senator WEICKER. Is it true that the trust fund balance will be $1 billion lower in 1985 than you estimated last May, when we made the last major overhaul?

Mrs. MCSTEEN. We do not expect that it would decrease to that degree. We do believe that the margin will be thin again for 1985, but certainly the 1983 estimates were higher than were anticipated. A lot will depend, as you know, on the demographic and economic conditions.

## REDUCTION IN WORK-YEARS

Senator WEICKER. Your budget recommends a reduction of 2,061 Social Security staff work-years, due to procedural and automation improvements. Isn't it likely that you will actually need more staff during the difficult period of transition to greater use of automation?

Mrs. MCSTEEN. We do not expect that we will need additional work-years for a number of reasons. As you know, the student benefits workloads will be phasing out in 1985, and that has been a major workload that we used to have to carry foward each year. We will have the SSI alert for aged Social Security beneficiaries behind us in 1985. All of those notices required by the Social Security Amendments of 1983 are going out this year, and we hope to take care of that particular workload in 1984. We certainly will have some work-year reductions, because 45 States have agreed to handle the face-to-face reconsideration reviews for continuing disability review cessations. Previously we had anticipated that those would be conducted by Federal personnel. So we anticipate being able to meet our workloads perhaps with the use of more overtime.

## BACKLOG OF DISABILITY HEARINGS

Senator Weicker. Your budget justification indicates that the backlog of hearings for disability cases increased during fiscal 1983. By the end of fiscal 1983, there were more than 173,000 cases pending, an increase of 20,000 backlogged cases.

Why does your budget material not estimate the number of cases expected to be pending at the end of fiscal years 1984 and 1985?

Mrs. McSteen. We estimate that the number of hearings pending at the end of fiscal year 1984 will be approximately 157,000 and, at the end of fiscal year 1985 approximately 115,000. We expect the pending to go down, due to the face-to-face reconsideration fair hearing process at the State level, and due to the reduction in the CDR workload.

I would like to recognize the fact that OHA has taken some management initiatives in the last couple of years which are paying off. The support staff has increased, and they are better trained. They have been able to increase automation in their field offices. Having better documentation for hearing cases after the face-to-face reconsideration will facilitate processing of the OHA workload.

It was not a significant item. Therefore, we did not put it in the budget for that reason.

## NUMBER OF PEOPLE TURNING TO WELFARE PROGRAMS

Senator Weicker. How many people who are removed from Social Security disability rolls turn to local or State welfare programs for support?

Mrs. McSteen. We do not have any precise figures regarding that. Tracking individuals, in that respect, would be extremely difficult, as well as costly and time-consuming.

## REFUGEE AND ENTRANT ASSISTANCE

Senator Weicker. I'm going to come back to some more questions on Social Security, but what I would like to do now is find out if Mr. Hawkes would care to address the refugee situation for a minute. Senator Chiles is due here in 5 minutes. Why don't we proceed to Mr. Hawkes and then come back to Social Security?

Mrs. McSteen. Very fine.

Mr. Hawkes. Senator, I have an opening statement that has been entered into the record, and I would just like to make a couple of comments, if I may.

For the Refugee Program in 1985, we are requesting $359 million. That's a reduction of $155 million from our 1984 appropriation and reflects that there will be an estimated 74,000 fewer refugees within the 3-year span of Federal responsibility in 1985 as compared with 1984. We are supporting the Lungren amendment, which is an amendment to the reauthorization of the Refugee Act that has passed the House. That amendment would require voluntary agencies to be legally and financially responsible for refugees that they resettle in this country during the refugee's first 90 days that they're here. We believe this would intensify the relationship between the voluntary agency and the refugee. Data that ORR has accumulated from a number of special projects has shown that the closer that relationship is and the longer the duration, the more likely it is that the refugee will go to work.

We are requesting $19 million in targeted assistance funds for 1985. By that time, we will have expended nearly $180 million in targeted assistance.

The Targeted Assistance Program was first put together to respond specifically to that very large number of refugees that came to this country in late 1979, 1980 and early 1981. Those people will have been here for at least 4 years now by 1985. The amounts of money in targeted assistance, aimed specifically at employment, we believe, will have by that time either worked, at which point it would not be needed any more, or if it hasn't worked, I would have great hesitation in putting additional funds of the magnitude that we have in 1983 and 1984 into a program that isn't working.

So the $19 million would serve to wind down the Targeted Assistance Program in fiscal year 1985.

We would request $13 million for education assistance to refugee school children and $8.9 million in health areas. The current dependency rate in the United States of refugees here 3 years or less is 57 percent. But that is a very misleading figure, because there are over 30 States where the refugee dependency rate is less than 30 percent. In fact, there are several States in which the rate refugees are on public assistance is about the same as the nonrefugee population. What we have, however, is one State that has about 35 percent of the time-eligible refugees and a 90-percent dependency rate. So that skews the entire program. If we take that State out of it, the dependency rate for refugees is about 35 percent which is, I believe not too outrageous a figure, considering the skills, the lack of English, the lack of skills, and the general cultural leap that these people must overcome once they are here in the United States.

At this time, I'd be happy to answer questions.

## LUNGREN AMENDMENT

Senator WEICKER. You are incorporating in the budget request the provision in the House-passed Refugee Assistance Extension Act mandating specific legal and financial responsibilities for voluntary agencies for refugees during the 90-day period after their admission—the so-called Lungren amendment, which you have already referred to. This provision is controversial and has not yet been adopted by the Senate.

What are the administration's reasons for supporting it?

And I think you have testified to some of those. Why are you proposing short-circuiting the authorization process through appropriation bill language, which you won't get? And if refugee legislation is not changed, how would you alter your budget request?

Mr. HAWKES. Well, to support the Lungren amendment, we would transfer $15 million to the Department of State, which they would supplement the R&P—the Reception and Placement—Agreement which they have with the voluntary agencies, to enable them to provide adequate food, shelter, and transportation and job counseling for the first 90 days. There would be no budget alteration if that Lungren amendment doesn't pass, because funds would not be transferred to the State Department. The money would remain in the State administered program budget.

## REDUCTION IN TARGETED ASSISTANCE AND SOCIAL SERVICES

Senator WEICKER. Targeted assistance and social services comprise the total budget to States to teach English, train, and place refugees into jobs. You are proposing to cut this budget in half in 1985 even though the 3-year population of refugees in the United States, which has formed the base of past allocations to the States, drops less than 20 percent.

Will this result in higher or prolonged welfare dependency and what services to refugees will be discontinued or reduced with the loss of these funds?

Mr. HAWKES. Senator, actually the social services money available in 1985 would be slightly increased from the 1984 level. The targeted assistance would be drastically reduced.

I think the Targeted Assistance Program was conceived specifically to handle over 200,000 refugees that came to this country in 1979, 1980, and 1981. What happened in that situation was that our resettlement capacity was exceeded by the tens of thousands of people that arrived here and they were resettled. That includes the Cuban and Haitian entrants who came in 1980. They were resettled at such a rate that English programs and job development and training programs were unable to keep up with them.

To acknowledge that one-time situation, targeted assistance was devised in 1982 to retroactively deal with that population.

We funded the program at a $35 million level in 1982. We requested $35 million in 1983, which was increased by the Congress to $81 million. Under the continuing resolution in 1984 we again expect to expend $81 million for targeted assistance.

If it hasn't worked, I don't see any reason to continue funding it at that level. Presumably it will have worked and those refugees and entrants who will have been here 4 years or more will have been aided and there would no longer be a need for the program.

It's not our intention to institutionalize targeted assistance as an ongoing part of the Refugee Program.

## MORATORIUM ON REVIEWING THE DISABILITY ROLLS

Senator WEICKER. The press is reporting—and we'll get back to Social Security for a minute—you are close to imposing an 18-month moratorium on Social Security disability rolls. What can you tell us with respect to your plans for handling the disability cases if a moratorium on reviewing the disability rolls were imposed through fiscal year 1985? How would that alter your budget request?

Mrs. McSteen. Mr. Chairman, the Secretary is considering alternatives to address the situation. She has not finally made that decision, and until I know exactly what the moratorium might be and the extent of it, it's pretty difficult to indicate how it might impact on the budget.

Certainly we have included in the budget administrative costs for processing CDR's, for continuing disability reviews, $259 million in 1984 and perhaps as much as $268 million in 1985. We should be able to certainly take care of that and if we do have a moratorium, of course, the lost program benefit savings could be substantial.

Again, it depends on the extent of the moratorium, but additional benefit payments could be perhaps as much as $1 billion.

## LEGISLATIVE CHANGES IN THE BUDGET REQUEST

Senator Weicker. Once again, you are assuming reductions in entitlement programs, primarily aid to families of dependent children, with estimated savings of $668 million. Aren't these proposals basically the same as the ones the administration submitted last year which were rejected by Congress; and why do you persist in requesting that these legislative changes be implemented through appropriations bill language?

Mrs. McSteen. Well, that has been the practice of the executive branch to assume that proposed legislation should be addressed through our budget. We have attempted to project into the budget our legislative proposals that are pending, feeling that we would be able to improve the program operation that way.

Senator Weicker. Well, I certainly don't intend to implement any change through bill language coming out of this committee. I thought we sent that message loud and clear last year.

Mrs. McSteen. I understand the position and I appreciate it.

## LOW-INCOME HOME ENERGY ASSISTANCE PROGRAM

Senator Weicker. According to the Congressional Research Service, the 1985 funding level proposed by the President for the Low-Income Home Energy Assistance Program would purchase 20 percent less fuel today than in 1981. Yet the $1,875,000 budget request is virtually the same as the amount appropriated in 1981.

How do you expect low-income families to make up for this cut in fuel assistance?

Ms. Ross. Mr. Chairman, I'm Jo Anne Ross and I'm the Associate Commissioner for Family Assistance, which has jurisdiction for the energy program. According to the figures that we have, the cost of energy over the last 2 years has, in fact, risen around 12 percent. We believe the $1.875 billion funding level will be sufficient to cover the increase that has occurred over the last few years, in part, because of the fact that, in the past, States did not spend the entire $1.875 billion for energy assistance.

As you know, under the statute the States have the ability to transfer funds out to other HHS block grants, as well as to carry funds over to the next year. In fiscal year 1982 the States transferred out $98 million to other programs, they transferred out $117 million in 1983 and they anticipate transferring out $88 million in fiscal year 1984.

Senator WEICKER. We just cleared a supplemental raise in the fiscal year 1984 funding to $2.075 billion.

Ms. ROSS. Yes, sir; the administration requested, just 1 month ago, that the Congress enact a supplemental appropriation of $200 million for the current year program.

The reason is the extreme weather conditions across the Nation. In fact through January, this winter was 16 percent colder than last winter for most States and 6 percent colder than normal.

We had extremely harsh conditions in certain areas of the country.

## ENERGY PROGRAM COSTS

Senator WEICKER. Yes; but No. 1, fuel costs are going up and your request remains the same. You're flying in the light of experience that you have had and from the point of view of fiscal planning you really should be taking the worst-case scenario; and this is a conservative administration, isn't it, Mr. Itteilag?

Mr. ITTEILAG. Yes, it is. [Laughter.]

Senator WEICKER. So that the worst-case scenario should be sticking out and, with this figure here, it's falling short.

Ms. ROSS. Well, Mr. Chairman, we estimate that the $1.875 billion figure would allow the States to provide benefits to the people who are served by the program, which would result in their spending a little over 4 percent of their income on heating energy. This is about the same percentage of income that is spent on heating by families who just miss eligibility for the program.

I think it's important also to keep in mind that this program was never intended—at least according to the history of the program—to be the sole source for energy assistance for these people. It was intended to be a supplemental program working in concert with the Aid to Families With Dependent Children Program, the SSI Program, the Food Stamp Program, and housing subsidies to provide the level of income that people need to meet certain expenses like energy.

But it's one of many programs. In fact, we have statistics which show that over two-thirds of the people receiving heating benefits also receive benefits from at least one other Federal program.

Senator WEICKER. Well, you want to make a bet as to whether you're going to be on the nose or whether you're going to fall short again next year? You see, obviously, we are going to appropriate the money. You're just doing a little sleight of hand from a budget point of view.

We're not going to deny these people whatever is needed to meet the legal mandate; but it's not good budgeting—that's really what I'm saying—in light of fuel costs going up, in light of the experience.

Now, every time I read the annual report of some company that either is in the fast food business or sells ice cream, they always tell you how the summer was unusually cold and the winter was unusually hot, and that's the way they explain the lousy bottom line figures.

I mean, it never fails, it just goes in reverse. That's what you're doing here. We went through this exercise last year. Let's just face up to the facts: You know that a good chunk of dough is needed for this program and we ought to budget for it.

Mrs. McSteen. The program does expire after September 1984.

Ms. Ross. As a part of the petroleum overcharge restitution fund legislation, we are requesting reauthorization of the program for 5 years.

### INCREASE IN FEMALE-HEADED FAMILIES ON AFDC

Senator Weicker. Your budget projects a decline of 83,000 AFDC recipients in fiscal 1985. Yet you expect female-headed families on AFDC to increase by 324,000 in fiscal 1985.

Is there a trend toward a greater percentage of those in poverty consisting of mothers and their children?

Ms. Ross. Mr. Chairman, we do anticipate that the entire AFDC caseload will be reduced, and that, in part, is due to the lag between the reduction in unemployment and caseload impacts. As you know, unemployment is reducing at an unprecedented rate now. It is usually a 4- to 6-month lag before the AFDC caseload is affected.

Addressing your question of the increased number of women in poverty, clearly we are seeing a situation where there has been an increase in female-headed households over the last several years. This is due largely to sociological factors.

More people are getting divorced and there are also more out of wedlock births or what is commonly referred to as a failure to form families in the beginning. We believe the principal solution for dealing with the increase of female-headed households, at least in terms of the effects of many of these women ending up in poverty, is to provide an opportunity for them to work.

We have statistics that show that only 25 percent of female-headed households that have a wage earner working full-time are below poverty. So clearly not working is tied in with the fact they're in poverty.

A second way that we are trying to address the issue of women in poverty is through our child support enforcement activities. While I can't speak to the specifics of what's happening there since Mr. Schutzman handles that program, we are working, as you well know, in the House and Senate on legislation to strengthen the child support initiatives that we have currently.

As far as the work proposals go for the AFDC Program, those primarily are targeted to self-support for women with young children who find themselves on the AFDC rolls. We have had some real success in many of the States which have chosen to implement our work proposals.

In the State of Oklahoma, for example, over two-thirds of the placements have been women with young children, who have left the AFDC Work Program and moved out into long-term unsubsidized jobs. In fact, their placement rate for that category of person was 200 percent greater than previous years, before they implemented the work proposals.

So that's what we're trying to address.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. All right. There are further questions which we will submit for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### CUT IN SOCIAL SECURITY STAFF

Question: Your budget recommends a reduction of 2,061 Social Security staff workyears due to "procedural and automation improvements." Why not wait until you see if the planned automation is actually implemented on schedule and functioning smoothly before cutting staff?

Answer: In the budget process we plan for any known changes in workloads or work processes. This includes expected workload increases as well as workyear savings which may result from procedural or automation improvements. In executing the budget we may find that actual experience differs from the estimates--in some cases we may have underestimated the workyears needed to process a particular workload, in other cases we may have overestimated them. Within the total budget we usually have flexibility to deal with these kinds of variations from the budget plan. Thus, for example, if we find during budget execution that implementation of a particular systems improvement designed to save workyears is delayed, we can continue to assign staff to that area by moving resources from another area where work may be less than in the budget plan. In addition, overtime can be used to meet unexpected workloads of a short-term nature.

We believe this kind of planning, including planning for expected staff reductions, makes more sense than waiting for changes to take place and reacting to them, with precipitous reductions in employment. Advance planning for staffing reductions allows us to make a smooth transition to new ways of processing work without disrupting service to the public and with minimal disruption to SSA employees. In this way reductions can be accomplished through normal attrition and by retraining displaced employees.

Question: How many staff overall will you be reducing as a result of your Systems Modernization Plan, over what period of time?

Answer: It is too soon to determine the total reduction in staff which will result from full implementation of the Systems Modernization Plan (SMP) or when all of the personnel reductions will take place. The SMP is a dynamic and evolving plan, consisting of many interrelated projects which are scheduled to be implemented over a period of time. The SMP is periodically refined and improved through annual updates that will keep it current, ensuring that it continues to be responsive to SSA's needs and reflects the most advanced technology available. In addition, before we can estimate the impact of any one project on staffing, it must be sufficiently developed that we know in detail what the changes will be and how they will affect current operations.

We now are developing detailed estimates through FY 1986, as part of the FY 1986 budget development process, of the effects of planned automation improvements. These estimates will update those included in the President's FY 1985 budget and will be based on the latest information regarding the timing and scope of expected systems changes.

Question: What impact will these staff reductions have on public services in your field offices?

Answer: A goal of the Systems Modernization Plan and other systems improvements is to provide more efficient, timely service to the public. We do not expect the budgeted reductions, related to workload decreases and procedural and automation improvements, to have adverse effects on SSA's public service. The budget is based on the amount of work we expect to process and the time it will take to do it. Decreases in certain workloads combined with processing improvements should enable us to provide better service to the public, even with a decrease in staff.

## IMPLEMENTATION OF TAXATION OF SOCIAL SECURITY BENEFITS

Question: The Social Security Amendments of 1983 require the taxation of benefits. Starting next January, you will be required to send millions of notices, similar to employer's W-2 forms, to recipients. How are you proceeding with computer systems changes necessary to implement taxation of Social Security benefits?

Answer: The agency is on target towards implementing the taxation aspects of Public Law 98-21--the 1983 Social Security amendments. The system changes are well documented and all component tasks required to implement taxation have been defined.

Specifically, we have completed the computer system changes necessary to compile the special data needed to prepare the actual benefit statement. These data are being stored on a data base known as the Payment History Update System. We recently confirmed through a comprehensive audit that the new data base does accurately carry the required information.

We are in the process of writing programs necessary to produce the tape that will be used in mailing out the benefit statement, and we are building a file which SSA's field offices can access online by December 1984 to enable them to answer any questions. We plan to commence mailing operations in January 1985.

All systems related activities required to fully automate the benefit statement process are on schedule at this time. We do not anticipate any problems in meeting this critical legislative mandate.

Question: How much is included in your fiscal 1985 budget to handle the influx of inquiries likely to result from taxation notices?

Answer: SSA's 1985 budget includes almost 800 workyears and $24 million to handle the large volume of inquiries expected to result from the mailing of taxation notices in January 1985. The inquiries will be received in a short period of time--January-April 1985--and an influx into the field offices could strain SSA's ability to process regular workloads. SSA plans to minimize the disruption in the field offices in several ways. First, we hope to reduce the number of inquiries by undertaking an effective public information campaign. In conjunction with the Internal Revenue Service, SSA hopes to improve beneficiary understanding of the notices to the extent that routine inquiries will be avoided. SSA is considering efforts such as public appearances, radio and television spots, newspaper columns and information booklets. In addition, SSA is developing and testing the design of the beneficiary notices in order to make them as clear and understandable as possible and thereby reduce the number of inquiries received in the field offices. Despite these efforts a large inquiry workload is unavoidable. Thus, SSA hopes to minimize the impact on its field offices by diverting a portion of the inquiry workload to non-field office sites throughout SSA. Although plans to accomplish this are still being developed, SSA hopes to establish telephone inquiry units and publicize the availability of toll free or minimal charge inquiry telephone numbers.

Question: Are you diverting resources from other areas in order to handle the additional taxation inquiry workload?

Answer: Because the brunt of this workload will be confined to a narrow period, we think it imprudent to hire large numbers of permanent staff to process the work. We're looking instead at areas from which we can free up staff resources for the work related to the 1983 Amendments, and we're exploring ways to manage efficiently the expected additional taxation inquiries.

In March 1984, we asked all operational managers to clear up pending workloads during FY 1984, and we required preclearance by the Deputy Commissioner for Operations of any plan which would add new work during the peak inquiry period during FY 1985. In both FY 1984 and FY 1985, SSA has identified several areas in which increased reliance upon automation and procedural changes would free up staff resources in FY 1985. Greater use of overtime from January through April may be another way we can manage staff resources for the inquiries workloads.

We're looking too at efficiently managing the workloads. This includes working with IRS to mount a joint public information campaign that will minimize the number of public inquiries when earnings statements are received. Another area under assessment is alternative telecommunications strategies to screen and handle inquiries, such as "900 service," special answering units, pre-recorded messages, and referral to IRS of tax related inquiries.

## MEDICAID COSTS OF CONTINUING DISABILITY REVIEWS

Question: When people who are removed from Social Security disability rolls turn to welfare for support, they and their families may also be eligible for Medicaid. What is this costing the Federal Government?

Answer: We do not have information about how many people who lose eligibility for Social Security disability benefits turn to welfare for support. As a result, I cannot define for you what effect this has on Federal expenditures for Medicaid.

## STATE AND LOCAL COSTS FOR AFDC ADMINISTRATION

Question: Under the AFDC program, the Federal Government pays 50 percent of State and local administration and training costs. In fiscal 1983, according to Congressional Research Service calculations, the Federal Government paid $87 per AFDC family for State and local administration in Wisconsin, $434 for administration in Oklahoma, and $715 for administration in Alaska. In Kansas and Oklahoma, States with approximately the same number of recipients, total administrative costs were more than twice as high in Oklahoma Why is there such a range among States with regard to Federal dollars spent on administrative costs? What causes such a variance?

Answer: The level of administrative cost is affected by a variety of factors, some within a State's control such as organizational and operational approaches which may affect cost efficiency and productivity and some beyond a State's control such as cost-of-living (economic), and density of population (demographic). The State data currently available to us do not allow us to determine what proportion of the variance is due to which factors.

Question: What was the range in 1982 and what is the projection for 1984?

Answer: The range in administrative cost per case per month in 1982 was from $87.25 in South Carolina to $504.00 in Oklahoma. We were disturbed by the very high cost per case in Oklahoma and requested an explanation. We were informed that the 82.3 percent increase between 1981 and 1982 was due in large part to an increase in the State's average number of employees with a simultaneous decrease in its average number of cases related to the Omnibus Budget Reconciliation Act of 1981. We were also informed that the Oklahoma legislature has recently been sensitized to the issue of administrative costs by a 1983 consulting firm study requested by the legislature, which noted the State's relatively higher salaries and lower caseloads for welfare workers, compared to other States.

The projection for 1984 is from $79.50 in Mississippi to $530.00 in Oklahoma (Alaska is projected at $529.00).

Question: What is being done to reduce the disparities in administrative costs?

Answer: As a precedent to establishing performance standards using an incentive/disincentive system, we are reporting to States how their cost performance compares relative to other States by establishing acceptable levels of performance we call "Desired Levels."

## AFDC WORK REQUIREMENTS

Question: Your fiscal 1985 budget repeats the AFDC work proposals recommended last year. By requiring all applicants to participate in job search and requiring most employable recipients to "work off" their welfare grant, you estimate Federal outlay savings of $17 million in fiscal 1985. Are these savings based on the assumption that workfare rules would deter people from applying for AFDC?

Answer: Savings are based on diversion of applicants who would otherwise become entitled to AFDC. This reduction encompasses more than "deterrence." Although it is likely that the requirements would deter employable individuals from using welfare as an alternative to work, State experience indicates that the main reason for caseload reduction is that people do participate in Community Work Experience Programs (CWEP). Available State data about the number of applicants and recipients diverted due solely to successfully finding a job during job search or during participation in work activities justifies our savings estimate. For example, in Washington State, 12 percent of job search participants found jobs within 30 days. Four States (Oklahoma, New York, Iowa and West Virginia) have reported that 20-30 percent of their CWEP participants are entering employment.

Question: How many people would be deterred from applying for AFDC because of work requirements?

Answer: States have not provided information specifically about the effect of the provisions in deterring AFDC applications. Deterrence itself is difficult to measure. States do report that larger percentages of applicants fail to pursue their application and significant numbers of recipients drop out of the work activities. Precise measures of how many more such instances than normal or the number attributable to the work provisions, are not available. They have been reporting a broader, more useful measure of the CWEP's effect in diverting applications and recipients from welfare dependency. This measure encompasses not only those who choose not to participate in the required activities (deterrence) but those who do participate and, therefore, are diverted to self-sufficiency through success in finding a job, whether through job search or because of increased confidence or improved job skills gained through CWEP activities.

Question: What costs are associated with these mandatory work provisions?

Answer: There are staff costs for the time spent working with the applicants and recipients in their job search and work activities as well as payments to applicants and recipients which allow participation. These latter payments would cover such items as child care and transportation. States have been impressive in their ability to keep these costs low to this program, frequently by drawing upon other resources. For example, a State might use the Social Services block grant or sponsors to pay some of the participation costs. We estimate the net cost of these activities to the Federal Government will be about $158 million in FY 1985. These costs to the Federal Government for title IV-A of $158 million is based on a 50 percent matching rate. Most importantly, however, these costs will be more than offset by savings from reduced caseload, producing an estimated Federal and State savings in FY 1985 of $171 million and $146 million, respectively.

Question: How many States currently require recipients to "work off" their grants?

Answer: Twenty-three States currently require AFDC recipients to participate in Community Work Experience Programs as a condition of eligibility.

Question: How many programs are Statewide?

Answer: Seven programs are Statewide.

Question: In the Statewide program, what percentage of the caseload is actually participating?

Answer: Based on informal State reports, we estimate that approximately 25,000 AFDC recipients are participating in CWEP. About 80 percent of these participants come from Statewide programs. Of the Statewide programs, we estimate that about 4 percent of the caseload (or 10 percent of the mandatory WIN registrants) are participating in CWEP. Still others are participating in other CWEP alternative work activities.

Nationwide, we estimate that one case in six is actively participating in WIN, or other alternative AFDC work activities. Under our proposals, we would expect 30 to 40 percent of the caseload to be participating in CWEP or alternative work activities. A substantial portion of the caseload would continue to be exempt from work requirements.

## WOMEN IN POVERTY

Question: What are you doing to counter the so-called "feminization of poverty"?

Answer: The Administration believes that a strong economy is the most effective means of reducing all types of poverty. One of the major causes of poverty since 1978 is the poor performance of the economy, including run-away inflation and recession. The Administration has made lowering inflation a top priority. In 1980, the annual inflation rate was 12.4 percent, and in 1983, it was 3.7 percent--an 11-year low. A lower inflation rate increases the purchasing power for everyone, including the poor. Unemployment has also been declining since 1982, and as the economy gets stronger, more jobs will become available for those capable of working, which will reduce poverty.

A key factor contributing to the poverty of families headed by females is the lack of child support from absent fathers. A recent Census Bureau study showed that in 1981, child support orders existed for less than half of the families with absent parents. To address this problem, the Administration has proposed legislation that will encourage States to pursue and collect support payments more aggressively. The Administration has proposed that Congress enact legislation which would mandate that States adopt enforcement techniques that have proven effective: mandatory wage withholding when an arrearage occurs; expedited judicial procedures to establish and enforce support obligations; and beginning in fiscal year 1985, State income tax refund offsets for the absent parent/spouse of AFDC beneficiaries. With enactment of the Administration's proposals, we expect that child support payments for both welfare and nonwelfare children will increase, thereby assisting families headed by females.

The most direct way to break the poverty cycle is by moving individuals from welfare dependency to employability and self-support. The welfare program changes already passed by Congress provide an opportunity for States to start work experience and job search programs. These programs give welfare recipients work experience and skills to allow them to become self-supporting. Over 36 States have implemented some type of work program. These programs have been found to be highly effective in making welfare recipients more employable. Four States, Oklahoma, New York, Iowa, and West Virginia, have reported that 20-30 percent of their CWEP participants are entering employment. The Administration's legislative package proposes to require all employable AFDC applicants to perform job search and all employable recipients to perform job search and participate in work experience programs as a condition of eligibility.

Question: How many poor families headed by women are not enrolled in AFDC? Why not?

Answer: There is no direct measure of the number of such families, and available data do not support a precise estimate. Census data for 1982 indicate that there were about 3 million female-headed household with children under age 18 below the poverty level. Our data for 1982 show that a monthly average of about 3 million families headed by women received AFDC. However, these numbers are not comparable because the poverty and AFDC measures have different bases. Poverty is based on annual income and is an unduplicated annual count. AFDC eligibility and caseload figures have a monthly basis and therefore undercount annual recipients.

However, there are a number of reasons why some of the families you refer to may not be enrolled AFDC. First, those who do not apply may choose not to do so because their income makes them eligible to receive only a small AFDC payment. Second, studies have shown that many AFDC recipients only receive welfare temporarily, and therefore these individuals may feel that it is unnecessary to receive benefits for only a short period of time. Third, persons may not apply to receive welfare because they feel that it is inappropriate to receive public assistance. Fourth, they may have income which, although excluded by Census, is counted in determining AFDC eligibility. Similarly, some resources available to the family, which may make them ineligible for AFDC, may not be measured.

## LOW INCOME HOME ENERGY ASSISTANCE

Question: According to the Congressional Research Service, households eligible for Low Income Energy Assistance spend about $20 billion a year for home energy. Of that amount, about $9 billion goes for heating costs alone. Based on this information, the President's 1985 budget request for the Low Income Energy Assistance program would offset only 20 percent of the cost of home heating for low-income households. What share do you feel we should be providing?

Answer: The Congressional Research Service figures quoted refer to all low-income households, as does the estimate that the $1.875 billion requested for FY 1985 would offset 20 percent of the home heating costs for these households. The Low Income Home Energy Assistance Program (LIHEAP) assists about one-third of all low-income households (i.e., households with incomes under the statutory maximum income standards) and a little less than half of all households eligible for heating assistance by income standards adopted by the States. We estimate that LIHEAP assistance offsets an average of about 40 percent of the heating costs of the households assisted. We think this is a reasonable offset, given the supplemental nature of the program.

Our request for reauthorization at $1.875 billion is based on consideration of the facts we have about the need for assistance, the other programs that also help meet this need, the flexibility given by the block grant to target assistance to households with the greatest need, and what States have done with LIHEAP funds in the past.

## DISABILITY APPEALS

Question: Last year, in the State of Connecticut, administrative law judges reversed two-thirds of the disability cases where individuals appealed the initial decision to deny them benefits. Is this a record of which we can be proud?

Answer: We have been concerned for some time about the disparity between disability decisions made by State agencies and by administrative law judges (ALJ's). We know that these results stem in part from situations where the beneficiary's condition worsens in the time between the two decisions. But part also resulted from a lack of uniformity in the decisionmaking standards applied by State agency personnel and ALJ's. We have made the guides uniform by issuing a series of rulings which are binding on both State agenices and ALJ's, and we expect these rulings to result in more consistent decisions. Another reason for the disparity was that the first face-to-face contact between the individual and the decisionmaker occurred at the ALJ level of review.

We are budgeting to implement a face-to-face evidentiary hearing process at the reconsideration level. Based on results of a pilot project conducted last year, we believe that this new process will result in more correct decisions earlier in the process.

Question: How much money is being spent on appeals?

Answer: In fiscal year 1983 the Social Security Administration spent approximately $290 million nationally to process requests for reconsideration of, and hearings on, determinations denying initial applications or terminating continued eligibility for disability insurance benefits. In the same year SSA spent approximately $110 million nationally to process reconsideration and hearing requests in SSI disability and blindness cases. (It should be noted that the first step in the appeal of a determination to cease SSI benefits is an ALJ hearing; only appeals of denials of SSI initial applications have a reconsideration.)

Question: How much could be saved if original denials were more in line with administrative law judge decisions?

Answer: We do not have that information. This question appears to assume that any initial determination that is overturned on appeal was incorrect. As explained above, some decisions that are allowed on appeal were correct when made but the beneficiary's condition worsens by the time of the ALJ hearing. Also, the lack of uniformity in decisionmaking standards has contributed to the differences in decisions at different levels.

Question: How much is in your budget to address the problem of continuing disability reviews?

Answer: SSA's administrative budget includes $259.3 million in FY 1984 and $267.9 million in FY 1985 to process continuing disability reviews (CDR's). These amounts cover the costs of selecting cases for review, performing the front-end interviews in SSA's field offices before the CDR begins, and conducting the CDR in State Disability Determination Services. In addition, for those cases resulting in termination from the rolls, the amounts budgeted include estimated costs for processing face-to-face evidentiary reconsideration hearings, and in some cases, hearings with administrative law judges.

Question: What is being done to avoid loading up the appellate process, which has been causing delays in getting hearings completed?

Answer: The suspension of periodic continuing disability reviews, announced by the Secretary on April 13, 1984, assures that no periodic reviews will be initiated until new disability legislation is enacted and can be effectively implemented. However, it also has the effect of relieving the workload pressure at the hearings level since it will eliminate new periodic review decisions from the hearings workload.

The second action announced--a continuation of benefits to beneficiaries who now have pending administrative appeals of their benefit terminations--will also greatly relieve the hearings backlog situation since it will eliminate the need for any further action on these appeals.

Because the overwhelming majority of Social Security cases appealed to the ALJ level involve initial or continuing determinations of disability, the April 13 decisions will greatly diminish hearings workloads.

## COSTS AND SAVINGS FROM "WORKFARE"

Question: Last year, you estimated $275 million would be saved by mandating "workfare" for recipients of Aid to Families with Dependent Children. This year, you estimate savings of only $171 million. What has changed to reduce the estimated savings from compulsory "workfare"?

Answer: The major change since the $275 million was estimated over a year ago has been in the number of people subject to the proposed work provisions. The estimated number of people affected was reduced for three reasons: 1) the overall AFDC caseload projections have been adjusted downward because of improvements in the economy. 2) the level of savings from the current optional work programs increased as more States implemented them, and 3) the savings attributable to the provision to expand registration to parents of children age 3 to 5 which were part of the $275 million estimate are now listed separately.

Question: How much more do you estimate it would cost to administer mandatory workfare programs at the State and local level?

Answer: The FY 1985 budget assumes administrative costs for the Administration's work proposals of $158 million Federal and $158 million in State costs. These costs are offset by gross savings of about $329 million Federal and $304 million State, producing net savings of $171 million Federal and $146 million State. We do not have specific States estimates of administrative costs for each State. The costs will vary among States based upon the number of mandatory participants, the level of services provided, the administrative efficiency of the State agency, and other factors.

Question: If "workfare" remains optional for State and local governments, should they be allowed to keep a share of the welfare savings, as an incentive to participate?

Answer: State (and local) governments do receive a substantial portion of the welfare savings resulting from the AFDC work programs. The actual State share varies depending upon the State's contribution to AFDC program costs. States now pay from 23 to 50 percent of AFDC program cost and average about 46 percent of the total. Because States are responsible for their costs, they benefit at the same rate for savings. So, if $1.00 is saved in welfare costs, on the average, the States save $.46.

The situation is different in the Food Stamp program because States do not share in the costs of Food Stamp benefits.

## SSI BANK ACCOUNT VERIFICATION

Question: In 1983 the Social Security Administration obtained consent forms from SSI recipients authorizing release of their Social Security numbers to the Internal Revenue Service. The object was to identify bank accounts of SSI applicants and recipients so that such resources could be verified. However, a U.S. Circuit Court of Appeals ruled that the forms were not obtained voluntarily and could not be used. What are your plans, if any, to revive this plan?

Answer: We are continuing to explore ways to improve SSA's access to accurate and complete information on the bank account resources of SSI beneficiaries and applicants. We still believe that bank account verification will help to prevent erroneous SSI payments and will continue to look for the most efficient methods of verifying in accordance with disclosure rules.

It should also be noted that the House, on April 4, 1984, passed H.R. 5362, Section 101 of which authorizes the IRS to disclose unearned income information from computerized files to any Federal, State, or local agency administering one of several programs including SSI.

## SSI VOCATIONAL REHABILITATION

Question: As a result of the 1981 Omnibus Budget Reconciliation Act, the Social Security Administration now provides funds only to reimburse vocational rehabilitation agencies for costs incurred in successfully rehabilitating SSI recipients. Successful rehabilitation is defined by a law as one in which vocational rehabilitation services result in performance of substantial gainful activity for a continuous period of 9 months. How has this law affected State vocational rehabilitation programs?

Answer: The Omnibus Budget Reconciliation Act (OBRA) of 1981 transferred primary responsibility for the vocational rehabilitation (VR) of SSI recipients to the Basic State Grants Program administered by the Department of Education under Section 110 of the Rehabilitation Act of 1973. In so doing, OBRA reduced the special funding for SSI VR. We are requesting $3,000,000 in our budget for SSI VR funding, the same amount as budgeted for FY 1984. We do not have data on which to base an assessment of OBRA's effect on rehabilitation programs.

Question: How has it affected SSI recipients?

Answer: State VR agencies no longer have to report to the Rehabilitation Services Administration the number of SSI recipients they serve, and therefore there are no national data available on numbers of SSI recipients being served.

## COST OF CHILD SUPPORT COLLECTIONS

Question: In 1982, total child support collections per dollar of total administrative expenditures ranged from $.63 in Oklahoma to $7.26 in Pennsylvania. The average ratio for the U.S. was $2.99. What accounts for this disparity?

Answer: The figures vary widely for a number of reasons. Those States that have been the best performers are those whose governors, State legislators, judges and other key officials have supported the program through passage of comprehensive legislation and emphasis on effective and efficient management practices.

We feel that the pending child support enforcement (CSE) legislation speaks to these problems by requiring States to enact enforcement practices of proven benefit and by providing financial incentives that reward performance in increasing collections in a cost-effective way. We have also begun a campaign with governors, other elected officials, and judges, to emphasize the importance of their leadership in achieving a successful CSE program.

## SYSTEMS MODERNIZATION PLAN

Question: The Social Security Administration is currently in the midst of a 5-year "Systems Modernization Plan" intended to upgrade computer systems. The 18-month "survival" stage should now be completed and the project is scheduled to be in the redesign phase. What progress have you made in implementing the Systems Modernization Plan?

Answer: In March the Social Security Administration completed the second year of the Systems Modernization Plan (SMP). During the first two years, the strategic directions outlined in the original plan were maintained. The SMP remains on schedule, showing progress under each of the four original programs plus a fifth program which was added to modernize our computer operations.

Our foremost objective for this 2-year period was to stabilize, turn around and reposition our data processing environment. That objective has been attained, and the Agency is now positioned to move forward with the transition to a modern data processing system.

The first 2 years yielded both tangible operational improvements as early projects were completed, as well as equally critical new disciplines, planning and control processes and an overall information and systems architecture for building future systems. Early efforts focused on establishing a foundation for a modernized system. Installing new host processors and direct access storage devices provided sorely needed operational enhancements as well as the hardware needed to begin the redesign of our antiquated, inefficient and difficult-to-maintain software. The new hardware has provided not only an environment for transitioning to state-of-the-art software systems, but also has allowed us to operate our current systems more efficiently and more responsively to the system users--and ultimately to the American public we serve.

Having set the foundation, we are now progressing toward building more "visible" parts of the modernized system--the telecommunications utility, the software, and database which communicate, process, and maintain earnings, entitlement, claims and ongoing eligibility information. In many respects, the next years present a greater challenge than we successfully met in the first 2 years. Integrating and coinciding the sophisticated technologies envisioned under each SMP program is an enormously complicated task. No automated data processing operation--in military or civilian government, nor in private industry--has attempted so thorough an overhaul of its information processing capabilities. The accomplishments by SSA in only 2 years clearly demonstrate to outside observers as well as many inside that the modernization is a reality. Our successes have reinforced our determination and confidence that the Systems Modernization Plan is indeed fully achievable. The data processing crisis which engendered the SMP has been averted, and substantial results have been achieved.

Following are descriptions of SSA's data processing environment before the SMP, the most significant improvements to the environment under the SMP, to date, and an analysis of the operational effect of SSA's data processing capability.

The Social Security Administration's (SSA) primary responsibility is to administer the nation's major income security programs. SSA maintains over 200 million Social Security records based on Social Security numbers issued. In FY 1983 SSA paid benefits to about 36 million Social Security beneficiaries and 4 million SSI recipients, issued 13 million new and duplicate Social Security number cards, processed 5.5 million new claims for benefits, posted some 200 million earnings items, processed appeals and changes to eligibility data. Before the initiation of systems modernization, the processing of these data were accomplished with 11 main (host) processors in Baltimore plus 11 more in the program service centers around the country, which represented technology developed in the 1960's. The system consisted of some 12,000,000 lines of computer code resident in over 12,000 software programs--software whose design and engineering reflected the technology of the 1950's and 1960's.

In this environment, nearly 20 days of computer processing was required just to implement annual cost-of-living increases; this year the increases were accomplished in 3 days. Response time to users in field offices on our telecommunications network peaked at 16 seconds; response time is now under 3 seconds. The "downtime"--inoperative periods--of our old network host computers peaked at 45 hours per month; currently there is effectively no network downtime on the new host computers. Reading the Master Beneficiary Record sequentially on magnetic tape took a minimum of 45 hours; reaching the same records on direct access storage devices will now require a little over 5 hours. In prior years, we were routinely 2 to 3 years behind in posting wage reports; this year we are fully current and are well into processing the 1983 tax year reports.

The projects which contributed most toward these improvements include:

Software Engineering Program

SSA has completed the first phase of defining and documenting total information requirements. A disciplined approach to a definition of our information processing requirements, known as top down analysis and business systems planning, is the necessary first step toward inventorying the automation needs for administering SSA's programs and then grouping those requirements into an arrangement which will dictate the logical structure for the new software systems. The methodology will yield an overall software design which will eliminate the redundant processing which occurs in today's software (e.g., duplicate benefit computations are accomplished separately in over 100 programs. Each program is dedicated to processing one discrete type of transaction such as a change in student status). The new design will consolidate functions so that editing data occur in one set of software, computations occur in one set of software, and so on. The benefits from this concept will be faster and fully automated implementation of new program requirements from legislative and policy changes. Because the concept of collapsing like transactions into common software underlies one future design, we are applying it also to some of our old software. As we make incremental improvements to existing software, we are combining functions whenever possible.

Total systems redesigns for several areas were competed, and design and development has begun. The systems now under redesign include the entire Annual Wage Reporting System and a Debt Management System. We will soon compete the redesign of the Enumeration (Social Security Number issuance) Systems. The Claims System is also being completely redesigned. All new systems will bring not only data processing efficiencies but also improvements in the accuracy of our processing, primarily through substantial elimination of manual, highly error-prone handling, and will save manpower through that increased automation.

While redesigning major segments of our whole software system, we also are making technical improvements in segments scheduled for later total redesign. Without changing the functions the old software performs, we are restructuring existing code to make it more easy to read--and thus, more easy to maintain--and to eliminate dead code that is no longer used or that has been supplanted by more recent code. These "software improvements" are accomplished using other software which operates automatically to standardize and document what functions the code performs.

All intermediate working files (data which passes from one program to another for further processing) and the major master files have been moved from a magnetic tape storage media to direct access (disk) storage devices. All software which accesses and updates these files has been modified to accomodate communications with the new devices. These improvements have reduced by almost half the number of programs per month which were abnormally terminated and which had to be rerun. The new storage devices reduced these "abends" by sharply curtailing the errors in data because of the higher reliability of the newer media and because the handling of magnetic tape is a very labor-intensive and error-prone activity. Data stored on direct access devices remain untouched by people.

Now that data are stored on the newer devices, we can take advantage of the more sophisticated and efficient method of direct access to data--a prerequisite for an on-line processing environment. Direct data access means that the field offices will have immediate access via their terminals to current data, and can effect changes to the data immediately; this makes faster and more accurate service to the public possible.

The manner in which we developed and revised software has never been subjected to the standards or controls which have existed for years in most other data processing environments. Defining and instituting discipline and controls, automating support for software development, and supplying terminals for each programmer are projects nearing completion. These efforts improve the productivity of our programmers, standardize the methods and results of software development, reduce software errors and provide a more professional environment for developing software. The standards and automated enforcement of those standards are applied both to software developed by our own staff as well as that developed by contractors. Software reliability, maintainability and adaptability are gradually being achieved. SSA's first on-line software system was acquired and installed. The system controls installment repayments from overpaid beneficiaries to the Social Security trust funds and the general funds.

### Data Base Integration Program

The transfer of data from magnetic tape to direct access storage devices is fundamental to software redesign. It is equally essential to designing state-of-the-art data bases. SSA maintains several hundred million separate records. Most files contain data that are present also in several other files. Basic identifying and entitlement data are recorded redundantly on multiple files which are then augmented with data unique to their original purpose. Combining and arraying data to eliminate redundancy and to improve the efficiency of accessing that data are the goals of the data base integration program. To accomplish this, the data must not only be rearrayed, but data base mangement software must be redesigned and installed for use by the applications software programs. The first step in our incremental approach to data base integration is moving data from tape files to direct access storage devices. Much of this effort is complete. Developing and implementing the software to access the data directly (that is, reaching the data needed directly rather than first reading all the data sequenced as must be done when data is stored on tapes) is the second stage. This software has been developed with both in-house and contractor support and it is being applied across our data files.

Completion of these two stages positions us for data base integration. A data base design architecture was formulated which will soon be developed and then implemented. The data base scheme responds to SSA's unusually enormous volume of data by minimizing redundancy and simplifying the applications programmer's access to the data.

## Data Communications Utility Program

The existing SSADARS telecommunications network which links SSA's field offices to the data center was improved with the nationwide upgrade of the high speed telecommunications lines and the replacement of the two host processors. These improvements increased line capacity by 200 percent and so eliminated the backlogs of messages which were once routine. The higher reliability of the new processors reduced response time to the system users from a peak of 16 seconds to under 3 seconds.

A procurement to acquire new terminals for the new data communications utility was developed and award should occur in the fall of 1984. The overall design for the new DCU has been set, and procurement for the new network has begun, with award scheduled for the fall of 1984.

## Capacity Upgrade Program

The main host processors in the data center are which are 1960's technology are being replaced by new processors; installation will be complete in early summer. Total processing capacity has been increased by 275 percent. The processors used by our programmers to develop and test software were also replaced. New solid state paging devices were added to the system, and programmers now have more than double the computer power and computing speed that they had with the obsolete test facility. We installed over 500 additional terminals for use by programmers and system analysts, and we are approaching our goal of a 1:1 ratio of terminals to programmers. We also completed the Agency's requirements definition for new high speed laser printers and communications devices and initiated the acquisition of these systems.

The nearly tripled computing capacity has yielded results: the 2-year backlog in processing annual reports of wages from employers is eliminated, overnight "catch-up" processing has largely been eliminated so field users are experiencing a much faster turn around time on their transactions input to the benefit systems; direct access to the master files will be implemented this spring so the field can give faster, more accurate service to beneficiaries; computer programmer productivity has been increased; and, there is now sufficient capacity to take on the job of redesigning our ancient software systems.

## Systems Operations Management Program

This fifth program was added to the SMP in its second year. It focuses on automating and modernizing the way our data center is operated. We have automated the scheduling of workloads run on the computers, installed an automated tape management program to control the location of magnetic tapes, and installed operating procedures on-line for use by personnel in the data center. All of these operations were previously done manually. Automating them reduced the risk of loss of data, reduced system failures, and allowed us to more efficiently utilize our increased computing capability. Also, upgrading our operating system software to correspond to new hardware is one of the primary activities.

Very few delays from the original schedule published in the first SMP have been experienced. We have made minor changes to some of the activities originally outlined, but the strategic directions set out in the SMP have been executed.

## ENFORCEMENT OF CHILD SUPPORT OBLIGATIONS

Question: In November, the House passed H.R. 4325, 422-0. This bill requires States to adopt several methods of enforcing overdue child support obligations, including: withholding a specified amount from wages, intercepting State income tax refunds due the parent on an AFDC child, and imposing liens against the property of a tardy parent. The Administration, in its FY 1985 budget, has also urged that these provisions be adopted. In addition, the Administration has recommended that the Federal match for child support enforcement administrative costs be reduced from 70 percent to 65 percent. Wouldn't such a reduction in the Federal match hinder the ability of States to implement mandated enforcement procedures?

Answer: Overall funding to States is not being reduced, therefore, we have no basis to expect the States to reduce their effort. In addition, the congressionally-imposed reduction in Federal financial participation from 75 percent to 70 percent has produced no demonstrable reduction in spending for program administration. On the contrary, expenditures have continued to rise.

The practices we have proposed have been proven to be the most effective and efficient means of enforcing and collecting child support. Available evidence, from jurisdictions where they have already been employed, indicates that their application can increase child support collections and concurrently improve the economy of program operations. However, we do recognize that in certain localities and States, the imposition of these practices would not be cost-effective. Thus, our bill provides for exemptions from the mandatory practices if a State or political subdivision can substantiate that the use of any one or more will not increase the efficiency and effectiveness of the program. Authority to grant an exemption would be given to the Secretary.

Question: According to Office of Child Support Enforcement reports, the Federal Income Tax Refund Offset program collected $168.9 million in 1982. What are the pros and cons of extending the program to non-AFDC families?

Answer: The major advantage of extending an IRS tax offset program to non-AFDC families would be to provide equal remedies regarding collection of child support arrearages to both non-AFDC and AFDC cases.

We are not proposing to extend the Federal offset process to non-AFDC cases because of the uncertainty in many non-AFDC cases as to the actual amounts of past due support. Since in non-AFDC cases there may be no governmental record of child support amounts previously owed and paid, expensive and time-consuming court or administrative hearings may be required to accurately determine the amount of the arrearage. Correcting erroneous intercepts of tax refunds for non-AFDC families would also be difficult. Since States will have already paid the money to the custodial family, they would then be unable to provide refunds to the taxpayer whose refund was incorrectly offset.

## IMPACT OF 1983 AMENDMENTS ON SSA'S SYSTEMS

Question: The 1983 Social Security Amendments contain provisions that call for major systems changes which require substantial automatic data processing resources. For example, taxation of Social Security benefits requires statements to beneficiaries of the amount of Social Security benefits paid during the year. Last year the Administration stated that it was "in the process" of identifying the level of additional resources needed, and that it did not anticipate that the implementation of the legislation would have an adverse effect on the 5-year Systems Modernization Plan because SSA was considering using outside contractors to augment SSA's systems resources. What has been the impact of the 1983 amendments on SSA's ADP resources and the Systems Modernization Plan?

Answer: It is true that, in the past, major legislation affecting SSA has preempted efforts to modernize SSA's computer systems. In recognition of this, one of SSA's major objectives since beginning the SMP has been to establish an effective, SSA-wide ADP planning system. For the past 2 years, SSA has developed a formal SSA-wide ADP Plan which describes in detail what SSA will accomplish in its computer systems area each year. A similar plan for FY 1985 is scheduled for completion this summer. Under this plan, work has been categorized into major areas including:

- o Major Cyclical Workloads
- o New Legislation
- o SMP Activity
- o Maintenance of Current Systems
- o Short-Term Improvements to Current Systems

Resources are allocated to the highest priorities first. New demands, such as legislation, can be carefully scheduled into the plan by reprogramming resources from lower priority activities. In essence, for the past 2 years we have been able to fully address SSA's cyclical, legislative and SMP initiatives while consciously limiting changes in the maintenance and short term improvement areas requested by users. As a result, we are successfully implementing work related to the 1983 Social Security amendments without any impact upon SMP projects or cyclical workloads. We have learned to manage our resources effectively so that our highest priorities are accomplished along with the most important of the short-term improvements.

## "STABILIZER" PROVISION

Question: In the 1983 Social Security Amendments, Congress sought to help protect the solvency of the Social Security system by enacting a stabilizer provision, which provides that, under certain conditions, cost-of-living increases will be the lower of the rise in prices or wages (instead of always being equal to the price increase as under prior law). A memorandum from the Social Security Administration's Office of the Actuary dated November 16, 1983 states that "there is a significant possibility that the stabilizer could be triggered in either 1984 or 1985, or even both years." What circumstances cause it to take effect?

Answer: Two conditions would have to be met before the "stabilizer" provision could affect an automatic increase in old-age, survivors, and disability insurance (OASDI) benefits.

The first condition that would have to be met is that the OASDI trust fund ratio, which represents the assets of the OASI and DI trust funds as a percentage of the annual OASDI expenditures, would have to be below 15 percent for benefit increases in 1984 through 1988 and below 20 percent in succeeding years. Except for 1984, the trust fund ratio that applies to the operation of the stabilizer in any year is defined as (1) the combined balance (exclusive of interfund borrowing) in the OASI and DI trust funds at the beginning of the year, including "normalized" tax transfers for the month of January, as a percentage of (2) estimated OASDI expenditures for that year.

For 1984, the law provides that the trust fund ratio shall be calculated as the combined balance at the end of 1984, including borrowed amounts and "normalized" tax transfers for January 1985, as a percentage of estimated OASDI expenditures for 1984.

The second condition that would have to be met before the stabilizer provision could affect a benefit increase, of course, is that the increase in average wages in the preceding calendar year would have to be lower than the increase in prices over the measuring period applicable to automatic benefit increases.

Question: Who determines that it will go into effect?

Answer: The law requires that the determination of (1) the trust fund ratio and (2) the applicable wage and price increases be made by the Secretary of Health and Human Services before November 1 of each year.

Question: How significant is the possibility that this provision will take effect?

Answer: The ratios for the December 1984 and December 1985 benefit increases have not yet been determined, but the trust funds are periodically monitored. Since that November 1983 memorandum to which you referred, we have developed revised estimates.

The current estimates for 1984 from the Trustees Report indicate that the trust fund ratio will be well above the 15 percent threshold. Thus, the December 1984 OASDI benefit increase will probably be based on the increase in prices only. The "stabilizer" provision will not be triggered.

For the December 1985 benefit increase, current estimates indicate that the trust fund ratio will be very close to the 15 percent threshold.

If actual experience is just slightly worse than that assumed for our intermediate estimates, the trust fund ratio could be below the threshold level. Before the 1985 benefit increase could be affected, however, a second condition must be met--namely, the applicable wage increase must be less than the applicable price increase. While this is a possibility, it does not appear likely at this time. The trust fund ratio and the applicable wage and price increases, with respect to the December 1985 benefit increase, will not be known until October 1985.

Question: If the stabilizer provision goes into effect, how and to what extent will it affect other programs?

Answer: If the "stabilizer" provision does limit the December 1985 benefit increase, then all OASDI beneficiaries would receive smaller benefit increases than they would otherwise. For those OASDI beneficiaries who are also receiving welfare-type benefits--for example, Supplemental Security Income benefits--the welfare benefits would, in many cases, be increased automatically to make up the difference in OASDI benefits. Therefore, if the "stabilizer" provision is triggered, expenditures for welfare-type programs would increase more than they otherwise would. The overall increases to these other programs, however, would be less than the savings to the OASDI program since not all OASDI beneficiaries receive welfare-type benefits.

## REVIEW OF DISABILITY ROLLS

Question: What criteria are used to determine which individuals on the disability rolls will be subject to annual review?

Answer: There are two major types of disability reviews: periodic reviews and medical reexaminations.

- Periodic reviews are scheduled at least once every 3 years in cases in which the person's impairment is not permanent and at longer time intervals in cases in which the person's impairment is determined to be permanent. Cases are selected randomly for review.

- Medical reexaminations are scheduled in cases in which recovery is anticipated. The time period between the allowance or continuance determination and the date of the reexamination is generally based on SSA's experience with the type of impairment involved.

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SSA does not schedule annual reviews in disability cases.

Question: What ever happened to the new guidelines promised last year for mental disability reviews?

Answer: Immediately following the Secretary's announcement that attention should be given to updating the eligibility criteria involving mental impairments, a special work group, composed of SSA personnel and experts from the mental health community, was convened to determine how that criteria could be improved. The work group just recently submitted its recommendations to SSA. We have accepted essentially all of the

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Question: Shouldn't you look at functioning capacity of retarded people, rather than simply IQ, in determining whether they should be eligible for Social Security disability assistance?

Answer: A mentally retarded individual's functioning capacity is a consideration in determining his or her eligibility for Social Security disability benefits. Although IQ testing has proven to be of significant value in evaluating disability, it is not used alone as a basis to deny claims. Care is taken to make sure that the test results are consistent with the evidence of the individual's daily activities and behavior.

We are close to proposing revised medical criteria in the Federal Register which concern, in part, the evaluation of disability for mentally retarded individuals. The proposed revisions in this area place greater emphasis on the consideration of the individual's functioning capacity in the disability determination. The proposed revisions will be published in the Federal Register.

Question: Legislation (H.R. 4170) has been reported out of the House Committee on Ways and Means which is intended to soften the impact of the continuing disability review process mandated by the 1980 Social Security Amendments. The Senate has held hearings on similar legislation. What costs are associated with this legislation?

Answer: The disability provisions in H.R. 4170 were reported out by the Committee on Ways and Means in H.R. 3755 which was passed by the House on March 27. We estimate that the bill might cost as much as $6 billion over the 5 fiscal years 1984 through 1988. The $6 billion estimate would apply if courts interpret the bill language to require that the medical improvement standard be applied retroactively, requiring reopening of cases decided over the past 3 years. If the medical improvement standard were required to be applied prospectively only, the bill would result in costs of about $3 billion over the first 5 years. These estimates include OASDI program and administrative costs plus SSI, Medicare and Medicaid costs.

Question: How difficult will its provisions be to administer?

Answer: Several provisions of the bill would be very difficult to administer. For example, under the medical improvement standard which would be provided by the bill it would be difficult to compare a person's current condition with his condition at the time benefits were awarded. The type of evidence used to make a disability determination in the past frequently differs from the type of evidence currently used because of changes in medical practice or technology. Consequently, comparison of the severity of a condition in the past with a current condition could involve measures made on two different scales with no means of converting from one scale to the other. Of course, if the courts required the medical improvement standard to be applied retroactively, tremendous workloads would be created because we would have to reopen all cessation cases decided over the past 3 years and make new determinations.

Another provision, which would extend coverage of the Administrative Procedures Act (APA) to SSA, could impede SSA's efforts to assure uniform standards in disability and other determinations.

Currently, although SSA is not subject to the public notice and comment requirements of the APA, SSA provides for public notice and comment on substantive rules. Interpretive rules and statements of policy are issued without notice and comment since the APA does not require it. Extending this part of the APA to the Social Security and SSI programs, because determinations of eligibility may be affected, would permit individuals to challenge SSA's determination of what policies are subject to the notice and comment requirements.

This would tend to confuse the State agencies and administrative law judges about the standards applicable to disability determinations and may greatly impede our efforts to assure uniformity in disability determinations. It would also add complexity in the administration of nondisability provisions since it would also apply to them. In addition, if the APA requirements are broadly interpreted by the courts, interpretive rulings which contain detail inappropriate for regulations would have to be issued as regulations.

Also, the provision that would require us either to recommend appeal of a circuit court decision with which we disagree or to acquiesce in the decision within the jurisdiction of the circuit court would create enormous practical problems. This would require that we keep track of applicants as they move through the decisionmaking process, determine which circuit's law should apply, and separately handle claims by jurisdiction. Special problems could arise where there are conflicting decisions within a single circuit, or a claimant or beneficiary changes residence while a decision on appeal is pending.

## SSI "ALERT" NOTICE

Question: Before July 1, 1984, the 1983 Social Security Amendments require the Social Security Administration to notify all elderly Social Security recipients "who may be eligible" for

SSI benefits of the availability of the program, and to encourage them to contact their district Social Security office. How many Social Security recipients do you estimate may be eligible for SSI, but not receiving it? How are you deciding who may be eligible?

Answer: We can't say precisely how many persons may be eligible. In the budget we estimate that about 75,000 new SSI recipients will be added to the rolls as a result of the notices mailed out by July 1984.

Beginning in February 1984, SSA began issuing notices to over 9 million Social Security beneficiaries aged 65 or older and whose Social Security benefit amount indicates that they may be eligible for SSI payments. As of April 10, 1984, 2.7 million notices have been mailed. We have received about 61,000 inquiries and 20,000 claims as a result of the mailings thus far.

The dollar limits used to select notice recipients were $334 for an individual and $492 for a couple. That is, if the Social Security benefit falls below these limits, SSA issues a notice to the beneficiary. The dollar limits are the current Federal SSI benefit rates of $314 and $472, plus $20 related to the monthly income disregard. In some States (10 at this time) the dollar limits used to select notice recipients is higher than the $334/$492 limits because the amount of those States' federally administered optional supplement are added to the Federal SSI benefit rate.

Question: Please give the text of the notice.

Answer: The text of the notice sent to the beneficiaries in most States and the Northern Marianas follows. In several jurisdictions which supplement the Federal SSI payment with an optional State payment, the notice to beneficiaries includes higher dollar limits:

"A Special Message About SSI

You may be able to get money under the Supplemental Security Income (SSI) program if you live in one of the 50 States, the District of Columbia, or the Northern Mariana Islands. (If you are already receiving SSI, please ignore this message.)

SSI is a program that pays monthly checks to aged, blind, and disabled people who do not own much and have little income. SSI is run by the Social Security Administration, but it is not the same as Social Security. Some people can receive money from both SSI and Social Security.

Are the things you own worth $1,500 or less? If you are married and living with your spouse, are the things you own worth $2,250 or less? (Don't count your home, car, insurance policies, burial plots and burial funds.)

Do you get less than $334.00 a month in income from all sources? If you are married and living with your spouse, do you and your spouse receive less than $492.00 a month? (Income means cash and checks you receive, such as your Social

Security check, earnings, pensions, or annuities. It can also mean items you receive from others, such as food and shelter.)

Are you a citizen of the United States or a legally admitted alien?

If you can answer yes to these questions, you may be able to get SSI in addition to your Social Security check.

Even if you answered no to some questions, you may still be able to get SSI.

To find out if you can get SSI payments, contact any Social Security office. The people in the office will help you file an application and tell you what papers you need. You can find the address and phone number of the office listed in your local telephone book under "Social Security Administration."

Question: Are persons who are informed of Medicare eligibility before their 65th birthday given information about SSI along with the Medicare notice. How?

Answer: Yes. Medicare enrollment packets are mailed to aged and disabled Social Security beneficiaries approaching Medicare entitlement (64 years 8 months). Since July 1983, the notice called "A Special Message about SSI," publication number SSA 05-11069, has been included in the packets.

The notices were revised to reflect the January 1984 cost-of-living increases and the rounding of the SSI Federal benefit rate. A further revision is planned for this summer to simplify the reading level.

## RESEARCH ON DRUG ADDICTS AND ALCOHOLICS

Question: Public Law 96-265 requires the Social Security Administration to undertake projects to determine whether alcoholics and drug addicts can be treated to prevent the onset of irreversible damage. What has SSA learned from this research?

Answer: Research to determine the feasibility of preventing the onset of irreversible medical conditions among alcoholics and drug addicts receiving SSI is currently underway. The first preliminary results of the research will be available in the fall of 1984. We expect to submit a report to the Congress in June 1985.

## SSI ENROLLMENT

Question: In 1984, for the first time since 1977, enrollment is expected to increase in the SSI program. (An average of 3.970 million persons are expected to receive federally-administered benefits in 1984, compared with 3.873 million in 1983. The projection for 1985 is another gain, to 4,019 million.) Why are SSI numbers growing after long, steady decline?

Answer: We projected an increase in the caseload as the result of the 1983 SSI amendments that provided for a $20 increase in the monthly benefit level and that required us to notify aged Social Security beneficiaries of their potential eligibility for SSI payments. In addition, based upon recent experience, we expect an increase in SSI blind and disabled recipients.

Question: Is the pool of eligibility persons expanding? If so, why?

Answer: We cannot say precisely whether the pool of eligible persons is expanding or contracting. However, we can make some inferences based upon past trends for persons who apply for SSI payments.

Other than the increase in the number of eligibles related to the $20 increase in benefit levels, the eligibility pool for SSI aged payments is probably decreasing. Each year, a greater proportion of persons turning age 65 are eligible for Social Security benefits that exceed the SSI income level. This is not a new trend. Even before the SSI program was a Federal program, as the Social Security benefits increased, the number of individuals in the States old-age assistance program declined.

The eligibility pool for SSI blind and disabled recipients may be increasing, based upon recent experience.

Question: Are relatively more eligible persons signing up? If so, who?

Answer: The outreach activity mandated by the 1983 amendments is causing some increase in the number of applications, but it is too early to say precisely what the overall result will be, since the outreach effort will not be completed until July 1, 1984. However, early reports indicate that about 1 out of every 4 people who respond to the notice apply for benefits. The overall response rate is about 25 percent.

## FOOD STAMP ADMINISTRATIVE COSTS

Question: The FY 1985 justification indicates that $122.3 million from the State and local administration account was transferred to the food stamp appropriation for the cost of certifying the food stamp eligibility of AFDC families. Please explain this transfer. How is it decided what share of general welfare administrative costs of a State are charged to the food stamp program and what share to AFDC?

Answer: Prior to the Food Stamp Amendments of 1977, AFDC households were automatically eligible for Food Stamps, so the AFDC households were certified for Food Stamp eligibility at no cost to the Food Stamp program. Due to the 1977 amendments, additional information is required to determine whether AFDC households are eligible for Food Stamps. The Departments of Health and Human Services (HHS) and Agriculture (USDA) agreed that the costs of this additional information should be charged to the Food Stamp program.

For FY 1984 HHS' budget submission included an amount sufficient to cover the cost, which has been transferred to

USDA. The amount HHS and USDA calculated was based upon a survey of 10 large States' administrative costs attributable to the food stamp certification activity. States were required to properly allocate their food stamps certification costs beginning in FY 1984. SSA issued instructions to States on August 2, 1983 to amend their cost allocation plans in accordance with the change in law.

## CHILD SUPPORT ENFORCEMENT COLLECTION PROCEDURES

Question: The FY 1985 budget estimated savings of $16 million in AFDC benefit costs associated with requiring States to implement certain child support enforcement collection procedures. Is this net savings?

Answer: Yes. These $16 million represent a net increase in collections for AFDC cases. Another $11 million net savings are realized due to lower administrative expenditures in the program as a result of the mandatory State enforcement practices. Total net savings as a result of these practices is $27 million.

Question: What costs would be associated with requiring mandatory procedures?

Answer: The procedures required are proven effective and efficient. On balance, we expect savings not costs. For example, a study done for SSA in 1980 by the University of Southern California found that the costs for administrative process jurisdictions are 60 percent lower than for court oriented ones. Judicial salaries and fringe benefits are higher than those associated with the administrative process. Also the number of cases adjudicated a day is lower for the judicial process, and it requires more support staff than does the administrative process.

Question: Would the majority of costs come from the 90 percent Federal match for development and implementation of computer systems?

Answer: It is anticipated that in FY 1985 the expenditure of 90 percent matching funds for computerized systems will rise by only $5 million as a direct outgrowth of the pending legislation.

Question: The annual report of the Office of Child Support Enforcement says that 44 States used income withholding as an enforcement technique in 1982. If this is so, why is there a need for a Federal law?

Answer: While 44 States have enacted legislation in some form, the variations in the statutes are significant and the authority is frequently not used. State statutes range from allowing voluntary withholding to, in a very few instances, requiring income withholding automatically upon accrual of a specified arrearage without the necessity of returning to court. Federal legislation would build on the most successful aspects of this disparate picture; would provide for national uniformity; would be applicable to welfare and non-welfare cases and to cases where the custodial parent and child (children) reside in one State and the absent parent in another; and would require enforcement.

Question: Why has the concept received so much attention and acclaim if it is already in use in most of the States?

Answer: The form of wage or income withholding advocated by the Administration and embodied in the House-passed bill (H.R. 4325) is not already in use in most of the States. On the contrary, it is only being used in about eight States today, and even here actual implementation is mixed.

Most commonly, the form of wage withholding being applied today is voluntary with the wage earner or is contingent upon judicial discretion in both establishing and enforcing a wage withholding order. This extensive judicial involvement, of course, also makes use of the withholding technique prone to all of the protracted delays and backlogs of an often overcrowded family court system.

## MONTHLY REPORTING IN AFDC

Question: In 1975, HHS initiated a monthly reporting project in Colorado that grew out of the Negative Income Tax Experiments and other research that showed that low-income families experienced much more fluctuation in earnings than was expected. It is my understanding that a number of studies on monthly reporting have been done since the Colorado study. What conclusion did these studies reach?

Answer: Following the Colorado study, research was conducted in Illinois, Massachusetts, Michigan and New York. Findings are available from New York and Michigan, and data analysis is still underway in Illinois. Research findings will not be available from Massachusetts due to funding cutbacks while the project was in progress.

Serious methodological problems limit the utility of the findings from Colorado, Michigan and New York. In Michigan, although the study was on monthly reporting (MR), the control group included a category of recipients who also had MR--those with earned income, a highly error-prone group. The studies in Michigan and New York did not examine the cost-effectiveness of limiting MR to certain categories of recipients. The findings, therefore, will not be widely applicable since 41 States now have waivers to exempt recipient categories for which MR is not cost-effective. In the studies in all three States, control and experimental group assignments were not random. Redeterminations were more frequent in the control groups than the test groups, and major changes in caseload and administering office organization occurred during the experiments.

Despite these methodological problems, the following limited conclusions can be inferred. The average payment per case and the agency error rate declined in Michigan. There were more grant changes and proportionately fewer recipient errors among MR cases in New York, and 95 percent of the savings under MR came from only two-thirds of the cases in Colorado (this finding supports regulations allowing States to exempt recipient categories for which MR is not cost-effective).

Question: Is there any proof that monthly reporting increases accuracy and reduces errors?

Answer: Historically, the most significant cause of erroneous expenditures has been the recipient's failure to report earnings and/or the earnings amount had changed from the amount that had been reported. Quality control data reveal that of every $4 misspent, $1 is due to earnings or unemployment benefits.

While it is too early to adequately assess the national impact of monthly reporting (MR) under the Omnibus Budget Reconciliation Act (OBRA) on error rates through our quality control system, we studied this issue prior to OBRA, comparing the earnings error rate of California--which had MR--with national totals (most of which did not have MR).

-- Where the presence of income was known to the agency, the national earnings error rate was double that of California, indicating that California's system did a better job of keeping current on earnings changes.

-- Where the presence of earned income was unknown to the agency, again, California's error rate on this item was less than the national error rate.

Since the implementation of OBRA, we do know that of the 41 States that have requested and received partial waivers of monthly reporting categories, all but four States (Texas, New York, New Hampshire and Virginia) report that MR is cost-effective. Thus, the savings realized by the elimination and reduction of errors are greater than the cost of operating the MR system.

Question: At what cost?

Answer: To date we have approved waivers for 41 States to do less than 100 percent monthly reporting. All but 4 of these States have shown monthly reporting to be cost-effective. The average benefit for each $1.00 spent on monthly reporting in waiver States is $2.45; the range is $.10 - $7.91.

Question: The 1981 Omnibus Budget Reconciliation Act requires all States to use monthly reporting for all AFDC recipients but permits them to exempt selected categories from the requirement with prior approval of the Secretary. How many States have requested waivers?

Answer: Forty-one waiver requests have been approved (none have been denied).

Question: For what groups do States require reports?

Answer: All States must require monthly reports from cases having earned income or recent work history. National quality control data reveals that one of every $4 erroneously paid is due to errors in these two categories. Other categories of cases may be exempted if the State can document that those cases are unlikely to experience change from month to month which would impact on eligibility or payment amount, and that the administrative costs of processing monthly reports would be unwarranted (for example, the cost would be greater than program savings which would accrue).

Question: Has HHS changed the redetermination of eligibility rules (once every 6 months) for persons required to report monthly?

Answer: HHS has not changed the redetermination requirement; however, States may apply for a waiver of the requirement under section 1115 of the Social Security Act and redetermine certain cases less frequently. In addition, in some States, the monthly report itself is sufficiently comprehensive (i.e., it contains all the information found in a 6-month redetermination) to satisfy the redetermination requirement.

## AFDC PAYMENT ERRORS AND FISCAL DISALLOWANCES

Question: In the AFDC program, States may be penalized for not reducing their payment error rates to the targeted error rate. These penalties require the States to pay the Federal Government the Federal cost of improperly issued benefits as measured by the quality control system. However, if a State can demonstrate that is is making a "good faith" effort to correct payment errors, the fiscal sanction may be waived. As of the most recent year for which quality control data are available, how many States have achieved their target error rate?

Answer: For FY 1981, the most recent full year for which we have complete data, 24 States reached their individual AFDC targets and 9 others were within 1 percentage point of their targets. Preliminary data for FY 1982 indicate that the number of States not reaching their targets will be no greater than the total for FY 1981. From a national perspective, this would represent further improvement in State management of the AFDC program because the FY 1982 target error rates for most States are lower, and, consequently, more difficult to meet. This improvement is further demonstrated by the 37 States that decreased their error rates between FY 1981 and the first 6-month period in FY 1982.

Question: In how many States have fiscal sanctions actually been applied and in how many States have the sanctions been waived?

Answer: To date no funds have been withheld from the 28 States subject to fiscal disallowances for FY 1981. All 28 States submitted requests for waiver of the potential disallowances based on having made a good faith effort. These requests are currently being reviewed. No funds will be withheld until decisions on these requests are made and the administrative appeals process has been exhausted.

Question: If all sanctions were applied and not waived, what would be the dollar savings to Federal Government?

Answer: The budget estimates that all sanctions are applied and includes dollar savings of $347 million in 1984 and $223 million in 1985. These sanctions are for the period FY 1981 to FY 1984.

Question: What is the status of any law suits brought by the States regarding the application of fiscal sanctions?

Answer: The Department has not yet applied quarterly control disallowances under the Michel amendment and there are no law suits currently pending. Each State will have full administrative appeal procedures available should any disallowance be imposed.

Question: As of the most recent year for which quality control data are available, what are the most frequent causes of AFDC payment errors?

Answer: The quality control system provides data on 43 primary elements of eligibility and payment amount. For FY 1981, the most recent year for which data are available, the most frequent causes of error were: problems related to reporting and recording earned income; proper registration for the Work Incentive Program (WIN); reporting and recording financial contributions received from other sources; obtaining and recording Social Security numbers for all recipients; proper reporting and recording of living arrangements; reporting and recording the presence or absence of a parent; and reporting and recording the receipt of Social Security benefits. These seven elements account for more than 60 percent of the national total of erroneous payments in FY 1981, with earned income the most frequent and costly element in error.

Responsibility for these and other payment errors was almost evenly shared by the agency (52 percent) and the recipient (48 percent). The most frequent cause of agency error was the failure to take a needed action, such as the case worker's failure to adjust a grant amount based on new wage information reported by the recipient. The most frequent cause of recipient error was failure to report information such as contributions from a family member.

Question: What are the reasons the States most frequently give for failing to meet their target error rates?

Answer: The provision of the Michel amendment which permits States to request a waiver of the disallowance for erroneous expenditures provides some examples of the reasons for failing to meet the target error rate that a State may cite. The examples include (a) extraordinary circumstances, such as natural disasters, strikes by agency staff, unpredicted workload increases and incorrect advice from Federal officials, and (b) a good faith effort on the part of the State to implement a corrective action plan reasonably designed to meet the target, even though the target was not met.

All 28 States subject to disallowance for FY 1981 submitted requests for waiver and most States submitted multiple requests.

Twenty-eight States submitted requests based on their good faith effort to implement a reasonably designed corrective action plan. Twenty States submitted requests based on one or more extraordinary circumstances; and the most frequently cited extraordinary circumstance was unpredicted workload increases.

Question: The conference report on the FY 1984 HHS appropriations bill suggested that the Department undertake a study of the problems of measuring error rates in welfare programs and that the Department report back before hearings on FY 1986 appropriations. What action has the Department taken on this study and what will be the scope of the study, if undertaken?

Answer: As Secretary Heckler reported to Chairman Weicker in a letter dated March 14, 1984, we have determined, after careful consideration, that further study of the quality control system is not warranted. Working together over the last 10 to 15 years, the Federal Government and States have successfully developed a methodology for measuring erroneous payments. The quality control system has been the subject of numerous studies and has undergone continual refinement and review over the years.

Question: Why does the budget propose to impose penalties in FY 1984 for excess AFDC errors that occurred in FY 1981, FY 1982, and FY 1983? Why weren't sanctions imposed sooner for back years?

Answer: Disallowances cannot be collected until all quality control data are obtained and error rates are determined. Historically, it has taken over a year after the close of the quality control period to complete this process. As a result, error rate data for FY 1981 were not available until early FY 1983 and error rate data for FY 1982 will not be available until late April 1984. Because of the problems caused by this delay, the Department issued regulations in October 1982 requiring the more timely reporting of quality control data by the States. These requirements, together with our streamlining of the process for handling State appeals of differences between State findings and Federal rereview findings, will result in more timely determination of error rates for FY 1983 and quality control periods thereafter. Consequently, we expect that during this fiscal year we will also be able to notify States of their FY 1983 error rates and begin the process of disallowing Federal financial participation for those States not attaining the 4 percent target.

Question: The 1981 Omnibus Budget Reconciliation Act made families with countable assets of more than $1,000 ineligible for AFDC benefits. Are States verifying the assets of recipients to insure that recipients are not exceeding the $1,000 (or lower State) resource limit? If so how?

Answer: Yes. AFDC has always had a resource limit as a condition of eligibility. Omnibus Budget Reconciliation Act of 1981 simply reduced the maximum from $2,000 to $1,000. States are required to insure that applicants and recipients meet this condition of eligibility the same as any other condition of eligibility, e.g., earnings, deprivation.

State eligibility workers verify the resource requirement by contact with banks, Assessor's Office, Registry of Motor Vehicles, etc. To assure the validity of the AFDC caseload on a continuing basis, we have our own quality control system which randomly samples cases on a monthly basis and subjects these cases to an independent and thorough review. Documentary evidence is secured to verify the various factors of eligibility.

## LOW INCOME HOME ENERGY ASSISTANCE

Question: The Low-Income Energy Assistance program was designed primarily to aid those low-income households with the highest energy costs. How does the Department identify such households? How effectively does it monitor compliance with this requirement of the program?

Answer: In its application for Low Income Home Energy Assistance Program (LIHEAP) funding, each State must assure that it will "provide, in a manner consistent with the efficient and timely payment of benefits, that the highest level of assistance will be furnished to those households which have the lowest incomes and the highest energy costs in relation to income, taking into account family size." The application must also describe how the State will carry out this assurance. These requirements are contained in the Low Income Home Energy Assistance Act of 1981.

Under the block grant, the States--rather than SSA--are primarily responsible for identifying and serving low-income households in accordance with the statutory requirements. The block grant provides greater discretion to the States than did the previous categorical energy assistance program. The States can best judge how to carry out the statute to meet the needs of their citizens.

In accordance with the statute, SSA gathers information on the number and income levels of households assisted. It monitors State implementation of the program to assure that the States properly carry out their programs within the flexibility provided by the block grant, and conducts a number of compliance reviews each year. SSA investigates complaints of a substantial or serious nature that a State has failed to use funds in accordance with the provisions of the statute or its assurances. Finally, SSA follows established procedures for hearings, investigations, and withholding of funds if a State does not use its allotment substantially in accordance with the statute and its assurances. We have found that State programs are, for the most part, well planned and well run, and that States are complying with statutory requirements.

Data provided in our November 1983 report to the Congress on FY 1982 LIHEAP show that the average LIHEAP recipient household has lower income and higher energy costs than the average low income household. This suggests that, on the whole, States are finding and serving those households for which the program was intended.

Question: Many States make direct payments to applicants for low-income energy assistance. How do these States check on recipients' use of this aid? How can they be sure that low-income energy assistance money is used to pay home energy bills?

Answer: Although nearly all States make some unrestricted LIHEAP cash payments, most States prefer restricted benefits, including payments directly to energy vendors on behalf of eligible households, vouchers, coupons, or two-party checks which households can redeem only for energy. States generally make cash payments only when restricted payments would be impractical--for example, for automatic payments to categorically eligible households, for payments to households which pay for their heat in their rent, or for small payments in the warmer States. States often include with such payments a notice stating that the payment should be used for home energy only. These payments generally do not cover the entire cost of a household's home energy bills.

There is generally no assurance that recipient households use the actual cash benefit payment for energy costs. However, most households have no choice but to make expenditures for home energy, and, generally, LIHEAP payments do not exceed these energy costs.

Some States, in fact, regard cash payments as reimbursement for fuel bills already paid. In that case, it may be appropriate for recipients to use LIHEAP benefits to purchase other necessities which they did not buy earlier in order to meet their energy bills.

Question: States may transfer up to 10 percent of their Low-Income Energy Assistance program allotments into other block grant programs and carryover up to 25 percent for use in another fiscal year. There has been a good deal of discussion about the transfer and carryover provisions of the Low-Income Energy Assistance program. How do you propose to change or limit these provisions-if at all?

Answer: We are not proposing a change in the current statutory transfer or carryover provisions. We believe that these provisions are important features of the flexibility provided by the block grants.

Question: In June 1983, 32 States told the Department of Health and Human Services that they intended to transfer over $100 million of their FY 1983 energy assistance funds into other block grant programs. Does this mean that those other block grant programs need more money? Or does it mean that energy assistance has too much money?

Answers: States are not required to tell us why they transfer LIHEAP funds to other block grants, or why they have not transferred funds from other block grants to LIHEAP. However, we think it is fair to conclude that most States feel that some other block grants, particularly the Social Services Block Grant, have greater need for the transferred dollars than LIHEAP does. We also believe it is fair to conclude that the energy assistance program is not underfunded as long as large amounts are transferred out and no funds are transferred in.

FUNDING FOR ENERGY PROGRAM

Question: The Department of Energy provided the following accounting of funds available from settlement of fuel overcharge cases:

$620 million collected so far
-200 million distributed to States for energy assistance and conservation per Warner Amendment to 1983 Continuing Resolution
=$420 million
-390 million referred to DOE's Office of Hearings and Appeals for possible refund to fuel companies
=$ 30 million available

Also, an original judgement of almost $2 billion was made against the EXXON company. However, this is being appealed, and it is unknown how much, or when, money will become available from this case.

Our information indicates that there is only about $30 million in the Department of Energy's fuel overcharge fund and that it's unlikely funds from the EXXON case will be available any time soon. How, then, is the Administration's proposed "overcharge restitution fund" supposed to finance a $2 billion a year program?

Answer: The proposed legislation authorizing the Petroleum Overcharge Restitution Fund states that when funds available from oil overcharge settlements and oil escrow funds are not sufficient to fund the Low Income Home Energy Assistance program and the Department of Energy programs, general funds will be used for this purpose. Therefore, the three programs will receive the amount Congress appropriates regardless of the timing of the oil overcharge settlements.

ALLOCATION OF ENERGY FUNDS

Question: OMB distributes Low-Income Energy Assistance funds on a quarterly basis. As of January 31, 1984, 10 States had obligated more than their first and second quarter allotments and another 14 States had used over 80 percent of them.

Our information indicates that by January 31st this year, 24 States had already used up at least 80 percent of the energy assistance funds alloted to them for the first 6 months of the fiscal year. Some were forced to consider closing the offices and laying off the staff administering the program until 3rd quarter funds are forthcoming. Is quarterly allocation really the best way to fund the program? Wouldn't some other allocation method be more efficient?

Answer: We believe the current system works well to provide funds when States need them. The fact that abnormally cold weather this winter caused a number of States to exhaust their annual allotment earlier than they had expected does not indicate a need to change the current grant award system.

Although we make grant awards to States on a quarterly basis, we do not award a quarter of each State's allotment in each of the quarterly grant awards. Before we make the first awards in a fiscal year, States provide to us estimates of when they will need their funds. We then make awards to States based on their estimated needs for each quarter. Most of the FY 1984 funds awarded to States were awarded in the first two quarters.

We issue single grant awards for the entire allotments to all Indian tribes and territories whose allotments are less than $1 million. These awards are made as soon as the grantee's application is found to be complete. (The Navajo Nation and the Association of Village Council Presidents are the only tribes and Puerto Rico is the only territory with an allotment over $1 million.)

We will advance a State's award schedule if necessary. Because of the extremely cold weather this winter, a number of States indicated that their original first and second quarter estimates were insufficient and requested accelerated award of some or all of their remaining funds. We made these funds available per the revised requests of these States.

## ENERGY ASSISTANCE BENEFICIARIES

Question: Low Income Energy Assistance has become one of our largest cash benefit programs, paying out $2 billion in FY 1984. How much of this cash has gone to recipients of other federally subsidized cash welfare?

Answer: Information based on the Current Population Survey indicates about a quarter of LIHEAP households receive AFDC, a little less than a quarter receive SSI, and about a tenth receive direct housing subsidies. Households receiving both AFDC or housing subsidies and LIHEAP have nearly all their heating costs covered by the combined assistance. Households receiving both SSI and LIHEAP have between 64 percent and 90 percent of their heating costs covered by the combined assistance. (These are national average figures.)

Overall, about half of LIHEAP households also receive some other form of cash assistance.

Question: Up to now HHS reports on cash income sources of AFDC and SSI recipients have left out home energy assistance. Why? When will these payments be included?

Answer: Current law prohibits the counting of LIHEAP assistance as income in determining AFDC or SSI eligibility and benefits. Since LIHEAP assistance may not be counted as income, information on LIHEAP assistance is not ordinarily collected as part of the AFDC or SSI case record. For this reason, reports on cash income sources of AFDC and SSI recipients do not include home energy assistance.

## SSI EXPERIMENTAL PROGRAM

Question: Under a 3-year experimental program that operated from January 1, 1981 through December 31, 1983, special SSI payments and eligibility for Medicaid were allowed to continue even though a disabled or blind recipient's earnings exceeded the substantial gainful activity level, $300 of counted monthly income. As the person's earnings increased, the amount of the cash payments decreased until they were gradually phased out. But eligibility for Medicaid was allowed to continue if the disabled or blind person could not work without the assistance and did not earn enough to pay for similar help. How many people were affected by this program?

Answer: About 300 to 400 persons per month received SSI benefits under the authority of section 1619(a) of the law. An additional 5,300 people retained Medicaid eligibility under section 1619(b) of the law.

Question: What happened to them when the program expired?

Answer: Under the demonstration authority provided by section 1110 of the Social Security Act, the Administration is providing SSI and Medicaid protection for those who were eligible at the end of December 1983. The demonstration project will provide this protection through December 1984.

## CHILD SUPPORT ENFORCEMENT

Question: According to the 1982 annual report of the Office of Child Support Enforcement, it cost the States about five times as much to collect $1 of child support for an AFDC family as for one not enrolled in welfare ($.61 compared to $.12). How could this ratio be lowered?

Answer: While the figures you quote come from the State reported data, their accuracy is questionable. A number of States do not accurately report the breakout of administrative costs between AFDC and non-AFDC cases. Also, the scope of what is classified as non-AFDC collections is a matter of State discretion and varies widely across the country.

However, it is clear that non-AFDC cases are more cost-effective for the client than AFDC cases. In many cases non-AFDC families are able to provide the IV-D agency with more recent, more accurate information on the absent spouse. As non-AFDC collections are paid directly to the family, the family has a stake in making the collections process easier for the IV-D agency.

The major problem relating to cost-effectiveness is that the current incentive payments made to States are not sufficiently linked to program performance. The proposed legislation would repeal the current incentive structure and replace it with one based on the ratio of collections to combined administrative costs, up to a maximum 10 percent for AFDC and 10 percent for non-AFDC cases, subject to a ceiling equal to the AFDC incentive.

## QUESTIONS SUBMITTED BY SENATOR PETE DOMENICI

### "STABILIZER" PROVISION

Question: Will the COLA stabilizer provision kick-in this year?

Answer: We don't think it will kick-in in calendar year 1984. The "stabilizer" provision of the Social Security Amendments of 1983 modifies the automatic annual benefit increases under the Old-Age, Survivors, and Disability Insurance programs, when trust fund levels are low and certain wage increases are less than applicable price increases. If the trust fund ratio--i.e., the ratio of OASDI assets to annual expenditures--falls below a specified threshold level, the automatic benefit increase is based on the lesser of certain wage or price increases. If the trust fund ratio is above the threshold, the benefit increase is based on the increase in prices only. The threshold level is 15 percent for the benefit increases in December of 1984-88 and 20 percent thereafter.

The law requires that the determination of (1) the trust fund ratio and (2) the applicable wage and price increases be made by the Secretary of Health and Human Services before November 1 of each year. The ratio for 1984 has not yet been determined formally, but the latest estimate which appears in the Trustees Report indicates that it will be well above the 15 percent threshold level that applies this year. Thus the "stabilizer" provision probably will not be triggered. The December 1984 benefit increase will almost certainly be based on the increase in prices, even if wages increase at a lower rate.

Question: How close to the 15 percent trigger will the retirement trust fund be?

Answer: As the 1984 Trustees Report states, "the inclusion of the amounts owed to the HI Trust Fund in the assets of the OASI Trust Fund at the end of 1984 virtually assures that the stabilizer provision would not limit the benefit increase for 1984..." The Trustees Report shows, however, that, even under favorable economic conditions, the ratio for 1985 will be very close to the 15-percent threshold (within 1 percentage point), and, under the pessimistic assumptions of alternative III, the stabilizer would limit benefit increases otherwise payable in December of 1985 and 1986.

### SSA STAFFING

Question: SSA's appropriations request for FY 1985 includes a decrease of 2,937 total workyears in all SSA programs from the FY 1984 level, and a decrease of 1,577 full-time permanent positions. Will this reduction affect Social Security district offices in any way?

Answer: Yes, the reduction in SSA's workyears and positions will affect the staff resources allocated to the district offices as well as other SSA components. We plan to achieve the reductions and at the same time maintain or improve our delivery of service to the public. This is because the budget request for

SSA reflects projected staffing needs--i.e. overall workyear requirements in FY 1985 are expected to be lower than in FY 1984 as a result of decreases in some workloads and projected savings from procedural and automation improvements.

For example, student workloads will continue to decline as those beneficiaries are phased out, as required by the Omnibus Budget Reconcilation Act of 1981. In addition, much of the work related to the Supplemental Security Income provisions of the FY 1983 Social Security Amendments will be behind us. Further savings are projected through improvements in work processes and increased automation, some of which are related to the Systems Moderization Plan. These improvements should result in faster, more responsive service to the public and should free up staffing resources for other work in FY 1985--such as for handling inquiries related to the taxation of Social Security benefits.

Question: Will the planned reductions in HHS Office of Secretary personnel have any effect on SSA personnel actions?

Answer: The planned reductions in HHS Office of the Secretary (OS) personnel are not expected to have any adverse effect on SSA personnel actions. If OS implements a mandatory placement program to assist employees affected by the reduction efforts, we will utilize that program when filling positions in SSA as vacancies occur.

Question: How many SSA employees are now working outside of SSA--i.e., in congressional offices, in State and local government, in associations such as the National Governors Association, or the American Public Welfare Association?

Answer: Below we have provided information on SSA employees that are currently working in non-Executive Branch institutions. We have separately identified those employees who are participants in formal development programs--e.g., Intergovernmental Personnel Act or Congressional Fellowship Program--and those employees on detail to another institution not associated with a development program.

| Formal Development Program | Detail |
|---|---|
| 11 | 2 |

FUNDING FOR THE ENERGY PROGRAM

Question: The Administration is proposing that the appropriation for the Low-Income Home Energy Assistance program be funded from the "Petroleum Overcharge Restitution Fund". How much funding from this source does the Department estimate will be available for FY 1985?

Answer: As of December 31, 1983, more than $420 million (including interest) were in oil overcharge escrow accounts in the U.S. Treasury. Of this amount, $394 million are currently the subject of formal administrative proceedings to provide claimants an opportunity for a hearing to determine whether they were economically injured by oil company actions and entitled to direct restitution. We expect determinations regarding these funds to be made soon. The remaining funds in the account are over $26 million.

We expect that an additional $5-$6 billion will be recovered from oil overcharges, and that the majority of these additional recoveries should occur soon. We expect that between 60 and 85 percent of these funds will not be needed for direct restitution to injured parties. This amount as well as the funds not needed for direct restitution from the $420 million discussed above will be available to the Petroleum Overcharge Restitution Fund.

Question: If these funds are not available for FY 1985, how will the program be funded?

Answer: Funds for the Petroleum Overcharge Restitution Fund would come from three sources: first, oil overcharge amounts now held in escrow; second, overcharge amounts received in the future as a result of settlements, court orders, and judgments; third, if sufficient overcharge amounts were not available in a fiscal year, the balance of funds would be made available from general revenues appropriations.

## "WORKFARE"

Question: A recent article in the Washington Post reported that workfare has not been widely accepted by the States. How many States have implemented workfare?

Answer: Twenty-three States have implemented Community Work Experience Programs (CWEP) for AFDC recipients.

Question: Are these programs Statewide?

Answer: The programs in seven States (Idaho, Michigan, Oklahoma, Pennsylvania, South Dakota, Virginia and West Virginia) are operated Statewide.

Question: How many AFDC recipients are participating? How many have found jobs as a result of the program?

Answer: Based on State reports, we estimate that approximately 25,000 are participating in CWEP. Perhaps three to four times that many have participated since the program's inception.

We do not have figures on how many CWEP participants have found jobs as a result of the program. Several States are reporting that 20 to 30 percent of the CWEP participants are entering regular employment, but not all these job entries can be directly attributed to CWEP participation.

Question: How may the Department make workfare more appealing to the States?

Answer: Our primary emphasis in making work experience programs more appealing to States has been on providing assistance to States on operational issues and providing an exchange of information on successful State practices. This effort has been undertaken on several fronts, including publications, training, conferences, technology transfers and onsite consultations.

Among the specific accomplishments are:

--A contract to provide free training to State and local welfare agency staff on work program management.

--Publication of a guide on CWEP Worksite Development and Utilization.

--Seventeen State-to-State technology transfers in FY 1983. Under the SSA Office of Family Assistance's technology transfer program, the Federal Government sponsors interstate travel by State and local staff to obtain information from officials with proven experience in developing and operating AFDC programs.

--Presentations at several regional and national conferences on AFDC work program activities.

This summer, we are sponsoring two national conferences on work programs for State and local staff. We expect approximately 350 people to attend and to participate in an exchange of ideas about successful work program activities.

In addition to these activities, we continually monitor the implementation of the AFDC work programs. When we identify unnecessary Federal impediments to implementation, we make policy changes necessary to remove them. Our basic philosophy has been to allow States the flexibility provided under law and to minimize the administrative burden on States implementing these programs.

## AFDC ERROR RATES

Question: The AFDC target error rate for FY 1983 is currently 4 percent, and is reduced to 3 percent for FY 1984 and thereafter. How many States are subject to these sanctions?

Answer: All 50 States and the District of Columbia must meet or fall below these target error rates to avoid quality control disallowances. The target error rate for Puerto Rico, Guam and the Virgin Islands remains at 4 percent for FY 1984 and thereafter. We do not have error rate data available for FY 1983 or FY 1984 at this time. In the last 6-month quality control period for which complete data are available (October 1981-March 1982); 10 States already had error rates below 4 percent. This is an increase from the 3 States below 4 percent in FY 1981. This indicates that these targets are attainable and States are taking the necessary action to achieve the target error reduction rate.

Question: Does the Department plan to take sanctions against States that do not meet their target error rates?

Answer: We fully intend to carry out the intent of the Congress as expressed in the Labor-HEW Appropriation Bill for FY 1980 as referenced in the Continuing Resolution for FY 1980 (P.L. 96-123), commonly referred to as the Michel amendment. The FY 1985 budget assumes that all disallowances will be taken.

SSA has notified the 28 States with error rates in excess of their targets for the first Michel period (October 1980-September 1981) of our intent to disallow Federal funds for erroneous expenditures in excess of the target. All 28 States submitted requests for waiver of the potential disallowances based on having made a good faith effort. These requests are currently being reviewed. Where we find that a State's documentation of its efforts to attain its target does not justify a good faith waiver the disallowance will be imposed.

DISABILITY PROGRAM INITIATIVES

Question: Is the Administration preparing any programmatic initiatives in the disability program this year?

Answer: On April 13, the Secretary announced a suspension of the disability review process until new disability legislation is enacted by Congress. The Secretary has pledged cooperation of the Department in securing legislation that maintains our commitment to fair and humane treatment of the disabled.

Currently, the House has passed a disability reform bill (H.R. 3755). The Senate has made assurances that it will act within the next few weeks. Programmatic changes are likely to result from any legislation which passes.

This legislation will follow-up the reforms that the Secretary announced in June 1983. The major improvements from the Secretary's initiatives include:

- o The review process, formerly almost entirely a "paper" review of files, has been replaced with increased face-to-face communication.
- o Nearly a million beneficiaries have been exempted from the periodic review process by recognizing their impairments as permanent.
- o Cases are now selected for review on a random basis.
- o Two-thirds of the mentally impaired have been exempted from review pending issue of new mental evaluation standards.
- o A top-to-bottom review of disability policies is underway in consultation with appropriate experts and the States.

Moreover, the Acting Commissioner of SSA, in her announcement of a Management Plan for FY 1984-1988, focused one initiative on the management of the disability process. Its objectives are to make sure that the program reflects the rapid changes which have occurred in the world of work, in medicine and medical technology, in vocational rehabilitation, and in the general health of the population. Specific objectives include:

- o Reviewing disability guidelines, procedures, and policies to ensure they are consistently interpreted and applied throughout the claims and appellate process.
- o Reviewing and revising the entire continuing disability review process.
- o Establishing a research and review mechanism to assure that adjudicative criteria are consistent with the latest advances in medicine and vocational assessment.
- o Focusing on the role of physicians and medical evidence in the disability program.

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## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### CONTINGENCY RESERVE

Question: I'm mystified by your request for a $10 million supplemental in fiscal year 1984 for the contingency reserve, despite the fact that you expect to return $60 million to the Treasury at the end of the year. I'm baffled by that request because last year you did not request any supplemental contingency reserve funds although you projected a return of only $12,177,000 to the Treasury. Can you explain the discrepancy?

Answer: There are significant differences between the budget picture this year (for fiscal year 1984) and last year (for fiscal year 1983) that account for the differences in the contingency reserve levels requested for each year. These differences are the following:

-- Last year the Administration requested a supplemental of $103,434,000 to cover the full costs of the October 1982, Federal civilian pay raise and other mandatory payroll increases. This year the Administration has asked SSA to absorb about one-half of the costs of the January 1984, Federal civilian pay raise and other mandatory payroll increases, and has requested a regular pay raise supplemental of $21,058,000 plus an increase of $10 million in the contingency reserve.

-- Last year when the Administration submitted its budget request, the Social Security Amendments of 1983 had not been enacted. This year the Amendments are on the books and there is much uncertainty about the impact of the Amendments on workloads and costs for fiscal year 1984.

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## UNOBLIGATED BALANCE LAPSING

Question: I note that once again this year you returned a very substantial amount of money to the Treasury under your "limitation on administrative expenses" account. In fiscal year 1982 you lapsed $58,229,000. Last year the total returned to the Treasury was $106,544,000. I recognize that this is only 3 percent of a total appropriation of $3.5 billion but it weakens your case for a contingency reserve of $50 million. Can you tell us why you lapsed such a large amount of money?

Answer: Of the $106,544,000 you cite, $50 million was for the contingency reserve. Although we had expected last year to have to use all but $12,177,000 of the reserve for workloads and State agency costs exceeding the fiscal year 1983 budget estimates, these higher workloads and State agency costs did not materialize. From our point of view, a contingency reserve is a reserve for contingencies. When there are contingencies we use the reserve. When there are no contingencies, we don't. In fiscal years 1980, 1981 and 1982 we used part of the contingency. In fiscal year 1983 we didn't have to use any of it.

Aside from the contingency reserve, we lapsed $56,544,000 of that portion of the annual appropriation which did not provide no-year authority. This constitutes a small 1.7 percent lapse. Some of the major factors involved in this lapse were:

-- State disability agencies spent less money than budgeted due to changes in policies and procedures during fiscal year 1983 that reduced continuing disability review workloads.

--We overestimated Federal average salaries in our budget.

-- We deferred spending we had planned, to establish headquarters and regional training centers for SSA staff, because we needed better cost/benefit information before moving ahead.

-- As a result of our efforts and new Administration policies on office space, actual costs were less than in the budget for space.

## WORK MEASUREMENT AND SSA STAFFING

Question: You plan to spend $3.7 billion in fiscal year 1985 for the administrative costs of a staff of 76,981. Obviously a modest increase in productivity could produce major savings in an organization as large as yours. How do you determine your staffing needs? Particularly, do any of your organizational elements use work standards based on your work measurement systems?

Answer: For decades productivity calculation has been an integral part of SSA's administrative budget process. A modest increase in productivity (+2.3 percent over the level projected for fiscal year 1984) is built into the fiscal year 1985 budget request. The recent facts on the productivity of SSA employees are shown in the table below:

| Fiscal Year | SSA Productivity | Workyears Saved (+) or Used (-) |
|---|---|---|
| 1982 actual..... | -2.4% | -1,415 |
| 1983 actual..... | +6.6% | +5,790 |
| 1984 estimate... | +5.4% | +4,680 |
| 1985 estimate... | +2.3% | +1,955 |

Work measurement systems exist in every major line component of SSA, and in a few staff components. With one exception we do not use engineered work standards; but, on the other hand, we do not simply project past experience with productivity into the future in making up our budget.

The bulk of SSA's workyear requirements (about 90 percent) are based on an analysis of workloads and productivity. At the front end, workload projections are developed by our actuaries and our research and statistics people. These projections include things such as claims receipts and estimates of beneficiaries-in-force, which represent the key indicators that influence the amount of work SSA can expect.

Once anticipated workload volumes are established, we look at the total workyears needed to process them. A workyear is the equivalent of one person working one full year.

In projecting total workyear requirements for future years, we start with a thorough analysis of base year experience drawn principally from our work measurement systems. For each of SSA's workloads, this includes:

1. A count of work units received, work units processed and work units pending at year's end.

2. The total time invested in workyears.

3. Production per workyear, a figure which indicates how many work units were processed for each workyear invested.

Given experience for a particular workload in the base year, the job is to determine how this will change and why. Among the factors we take into consideration here are anticipated systems improvements and changes in agency policy and operational procedures which will affect the production per workyear for various workloads. Also considered are indirect factors, such as additional inquiries or training, which might be associated with legislative change or a particular administrative initiative.

To illustrate hypothetically how we project workyear requirements, suppose it takes a claims representative in a district office an average of 1 hour to complete an application for benefits. The production per workyear is then 1,780 since there are 1,780 hours in a workyear. (An employee is paid for 2,080 hours a year, but considering annual leave, sick leave, on the average an employee works 1,780 hours a year.) Suppose we estimate that a change in agency operational policy relating to disability claims will "save" the claims representative an average of 10 minutes per application. As a result, it will take an average of 50 minutes per application and the production per workyear will increase to about 2,136 (1,780 hours per workyear multiplied by 60 minutes equals 106,800 minutes--106,800 minutes divided by 50 minutes per application equals 2,136 applications per workyear). This new production rate per workyear will be applied to the anticipated number of work units to determine future workyear needs for this workload. This example is hypothetical and oversimplified, but it does give a feeling for how we develop our budget estimates.

Question: Typically, workload based budgets such as SSA's are based on work standards, or "should-take" time to accomplish its activities. These are work standards based on careful measurement of the time required to perform an efficiently designed process. I understand that SSA's work measurement systems record actual experience, or what might be characterized as "does-take". Could you not establish "should-take" times that could be used in budgeting?

Answer: SSA's work measurement systems do record actual experience which represents the time it "does take" to process the Agency's workloads. However, this "does take" time is not built indiscriminately into our budget estimates.

As part of the productivity analysis outlined in my response to the previous question, we take a careful look at "does take" experience. We have available a lot of historical data which give us a good sense about the time it "should take" to process workloads. In addition, our management and budget people spend a lot of time physically surveying operations, and we have a group of industrial engineers who look at special problem areas.

To reiterate a point made earlier, we also modify processing times in our budget projections to take into account systems, policy and procedural, and other changes we expect in future years.

Question: Since inefficient practices would not normally be acceptable bases for establishing work standards, what does SSA do to assure that efficient and appropriate procedures are being used before the work is measured?

Answer: SSA uses a number of different approaches to assure that established procedures are being followed correctly and that the established policies and procedures are effective and efficient. For example, all district and branch offices are scheduled for periodic "comprehensive review" visits. During this time the area director (who is responsible for several districts) and a team from the regional office observe the work processes, examine the files, study the workflow, etc. The comprehensive review closes with a meeting with the district manager who is given action items in order to improve office procedures and efficiency.

Work measurement and productivity data are used as indicators by the Office of Field Operations in headquarters and by regional office staffs in their ongoing monitoring of field office activities. These data quite often are used to detect offices that may not be following proper procedures and are in need of a special purpose visit to address specific problems. Some area directors have established area operations analysts to assist in these efforts. Part of their job is to identify inefficiencies in individual offices and, based on knowledge about procedures that work in other offices, suggest ways to correct the inefficiencies.

Another way we try to improve our procedures is through special studies. For example, we have a small staff of industrial engineers in SSA's headquarters who use scientific management techniques to improve workload processing and employee utilization. This staff takes on projects identified by SSA's Executive Staff. For example, recommendations from the industrial engineers resulted in savings and improved efficiency of mailroom operations by consolidation of SSA headquarters mailroom functions and changes in the way mail was distributed. This group currently is involved in a study to develop a work measurement system for SSA's teleservice centers, including measures of productivity.

SSA's Office of Assessment (OA) also plays a role in improving Agency policies and procedures. The primary goal of OA is to improve the accuracy of payments issued by SSA. As part of this process, OA also monitors the health of SSA operations by monitoring compliance with existing policies and procedures and appraising their effectiveness. OA works with the operating components to pinpoint problem areas, and, if necessary, corrective actions and/or changes in policies and procedures are recommended.

## PRODUCTIVITY

Question: The fact that some field offices have much higher productivity than others seems to call into question whether all offices are using the most efficient procedures. Even in areas which have similar geographic and demographic characteristics, the productivity differences can be dramatic. For example, the Decatur, Ga., office produces about 38 percent more work per person than your Savannah, Ga., office according to SSA 1982 internal reports. What is SSA doing to determine why some offices can produce so much more than others?

Answer: SSA has a two-pronged initiative underway to address variations in productivity:

1. SSA staff analyzed the variation in regional unit times for FY 1983 and identified, for each region, those workloads which had the most potential for productivity improvement. The regions are identifying the factors which cause their high unit times in these designated workloads and are developing specific action to streamline the workloads, and thus reduce unit times. Staff will review the regional analyses and actions for possible wider application.

2. SSA identified 21 high-performing, highly-productive district offices and is sending four-person teams to each office to determine the specific practices which allow the office to achieve high productivity. The visits will conclude in June 1984. All of the observed practices will then be considered for wider application to improve productivity in less productive offices.

Question: What steps do you have planned to implement staffing adjustments that put a priority on productivity and what's your timetable?

Answer: We do put a priority on productivity, which is taken into consideration when SSA develops the workyear and staffing projections included in its budget request. We also take anticipated productivity improvements into consideration when we distribute resources among SSA components. We then track our performance via monthly reports which compare actual experience to budget plans.

In FY 1983, SSA productivity increased 6.6 percent. Our budget projects further improvements which amount to 5.4 percent and 2.3 percent in FY 1984 and FY 1985 respectively.

## WORK MEASUREMENT

Question: In those parts of the SSA organization where you do not use work standards for determining staff needs, what approach do you use, and what are the barriers to using work standards?

Answer: SSA uses work measurement data to determine approximately 90 percent of its workyear requirements. The SSA Integrated Work Measurement System measures both work output and the distribution of labor required to process the work. Work output consists of counts of units of work processed, e.g., retirement survivors insurance claims, disability insurance claims, supplemental security income changes of address, disability insurance hearings, etc. In preparing the budget, SSA counts the work units for 68 different agency level workloads. The amount of employee time required to process a unit of work of each of the 68 workloads is measured either by work sampling techniques or by a full 100 percent accounting for employee time. The Integrated Work Measurement System enables SSA to account for the amount of the average employee time used to process a unit of work for each of the 68 workloads for the base year period.

The base year work measurement data is the starting point for estimating future workyear requirements included in SSA's budget request. The base year unit time for each workload (average employee time required to process a unit of work) is adjusted for anticipated changes in the way work is processed. The major reasons for adjustments are the following:

- -- Policy changes required by law or regulation that will result in more or less employee time spent on each unit of work.
- --Increased use of computers in processing work units.
- --Changes in work flow and other procedural changes.

The adjusted unit times, in combination with estimated workload volumes, enable SSA to calculate workyear requirements for the budget.

There are a number of reasons why it would be difficult for SSA to use work standards;

-- There are variations in unit times in different parts of the country because of demographic factors. For example, the district offices in Appalachia are very familiar with black lung claims policies and procedures and can process black lung claims efficiently. Offices outside this area receive few of these claims and because of their unfamiliarity with them cannot process them as quickly. In some States, in processing supplemental security income claims, the district office must elicit information from claimants pertinent to State supplemental payments that are paid by SSA on behalf of the States. These claims require more employee time than supplemental security claims processed by district offices in States where the States make their own supplemental payments. Varying educational levels in different parts of the country affect the amount of assistance required by claimants in completing claim actions, and this affects the amount of time district office employees must spend on processing work units. Demographic factors contribute significantly to variances in unit times in different areas of the country.

-- The nature of the work force is different in different parts of the country. In some areas, Federal salaries are high relative to the private sector and SSA can attract higher qualified employees. These employees are more effective and more efficient than in areas where it is difficult to recruit highly qualified employees. SSA must make regional allowances in unit times where its work force is not as efficient as in other areas of the country.

-- SSA is on the verge of fundamental changes in the way it processes much of its work. The Systems Modernization Plan will result in a series of improvements in employee productivity. For some period into the future, SSA will not experience a stable period in which to evaluate and establish unit processing times that can be expected to last for any appreciable period of time.

-- Frequent changes in law and regulations result in changes in policies and procedures that affect the amount of employee time required to process a unit of work. This unstable procedural environment coupled with the major systems changes underway would make it very difficult to establish stable unit processing times.

## CASE MANAGEMENT CONTROL SYSTEM

Question: In its June 21, 1982 response to GAO Report HRD-82-47, SSA agreed that productivity goals were desirable for field operations, but emphasized that caution must be exercised in establishing such goals due to the differences in local practices and population served.

SSA further described the Case Management Control System as a management information enhancement project which would address local differences and which had to be complete before setting individual field office goals. What is the status of the Case Management Control System and when do you expect to establish productivity goals at the office level?

Answer: The Case Management Control System (CMCS) is developing in stages from an initial simple workload control to an eventual more detailed integrated work management system. This ultimate system will not be operational until 1988 or later.

Currently, the regions are analyzing workloads with high unit times to identify factors--both controllable and "uncontrollable"--which cause local productivity variation. As we come to understand the dynamics of local productivity, and as we improve our local management information, we will be better able to develop local productivity goals. However, we are not now able to determine when productivity goals will be set at the local office level.

Question: Will the Case Management Control System allow you to distinguish productivity differences attributable to poor performance from productivity variations due to factors such as case development practices, populations served, and language barriers to facilitate the establishment of individual field office productivity goals?

Answer: The Case Management Control System (CMCS) will develop in stages from an initial simple workload control system to an eventual integrated workload management system. In the initial implementation, CMCS will function solely as an automated control system, i.e., one that tracks workload and can provide simple counts on pending workloads. As this stage is completed, work can begin on a broader Workload Management System (WMS) that receives data from CMCS, and that can support data analysis and generation of management information based on data furnished by CMCS. Eventually, WMS would be integrated with other support systems (such as time and attendance, work sampling) and would be able to produce the type of performance data identified in your question. We do not see this ultimate capability as being available until 1988 or later.

Question: Although the Case Management Control System will generate future SSA productivity measures, that system will not be in place until late 1985. What interim efforts are planned or underway to improve current field office productivity measures generated by the Field Office Work Measurement System?

Answer: The work measurement system used to measure field office productivity is under continuous review, and changes are made to capture information on new workloads and new work processes as needed. Refinements are made in the system whenever experience indicates these may result in better and more useful information. Surveys are conducted periodically to validate the integrity of the data collection methods and the data collected.

Several years ago we designed the claims system to automate counting of RSI, DI and SSI claims received in district offices. Efforts are currently underway to derive computer generated systems counts for post-entitlement workloads and to provide additional information on new claims. We expect these efforts will be complete before the Case Management Control System is in place. Computer generated work unit counts are more accurate than manual counts and are less costly to obtain.

ESTIMATING STAFF NEEDS

Question: How does SSA determine the amount of staffing adjustment necessary for reasons such as legislative change, workload variation or systems improvement. For example, in the FY 1985 budget you decrease the payroll by 459 workyears because of a FY 1984 "nonrecurring" backlog of high priority post-entitlement workloads, (pp. 191; B2c). Explain how those workyear estimates were calculated

Answer: To determine the impact of any anticipated changes on our total workyear requirements, we generally look at three things. These include the impact on workload volumes, the impact on direct processing times or production rates, and the impact on indirect needs for things such as inquiries or training. In many cases, we actually break this all down to a change in the number of minutes required for each factor involved.

Regarding the FY 1985 decrease associated with nonrecurring work, let me explain in general terms what happened.

Over the past few years, backlogs have built up in three SSA workloads:

-- Automatic earnings reappraisal operations, where we give beneficiaries who continue to work credit for higher earnings after entitlement.

-- Earnings enforcement operations, where we compare earnings reported by employers against beneficiary records to detect possible overpayments.

-- Reduction factor adjustments, where benefits which have been reduced based on retirement age are adjusted for months in which the beneficiary did not receive a social security check because earnings exceeded the allowable limit.

Each of the above workloads backlogged because of delays we had experienced in posting annual earnings to our records. These delays were caused largely by systems, or ADP, problems.

In FY 1984, SSA requires additional resources to complete work backlogged in the above areas for earnings finally posted through calendar year 1982. In FY 1985, a reduction of 459 workyears occurs because we get back to a more normal level for earnings-related workloads, in this case one year's earnings only, for calendar year 1983.

Question: Describe the process SSA follows during budget execution to monitor its workload and staff usage. Does SSA compare actual workloads and staff usage against its budget projections? How have staff projections fared against actual staff requirements? What analysis is done to identify reasons for the differences between projected staff needs and actual staff needs?

Answer: SSA has several reporting mechanisms in place to monitor its workloads and staffing and to compare actual experience against budget plans. I will briefly discuss a couple of these reports:

-- Our monthly Workload Analysis Report provides analytic data, at both the individual component and SSA levels, on workloads, workyears and production rates. We use this report to compare actual experience to budget plans so we can make appropriate adjustments in our internal distribution of resources as the year progresses.

-- Our Monthly Indicators Report provides a lot of information that we use in the budget execution process. This includes a comparison of current to past year's unit times for various workloads, and trends in selected workloads over a three year period. Also included are data on benefit payment accuracy and statistics on benefit outlays and debt collection. We use the Monthly Indicators Report to track how actual performance compares to the past year's experience so that adjustments can be made during the operating year.

In assessing how our staff projections fare against staff requirements, we focus on total SSA workyears rather than the number of employees we have on-duty at any given time. Unlike staff on-duty at a point in time, total workyears take into account seasonal and peaking employment, a good example of which is the seasonal hiring SSA does each year to handle its cyclical annual wage reporting workload. Total workyears also include overtime, upon which SSA projects increased reliance over the next few years.

The FY 1983 column of SSA's FY 1984 budget included 88,933 workyears for all of the Agency's programs. SSA actually used a total of 89,299 workyears, for a variance of only 4 tenths of 1 percent.

Within the totals I just mentioned, of course, there are more signficant variances if one looks at specific programs and workloads. The reporting mechanisms I described earlier, coupled with continuous review and analysis of actual performance at all levels within SSA, allow us to keep track of changes from our budget plans. These changes are incorporated, along with everything else I have mentioned, into future budget projections.

## AFDC PROGRAM--STATE ADMINISTRATION

Question: You plan to provide States and localities over $1 billion in fiscal year 1985 to administer the AFDC program, an increase of $45 million over the current budget.

Title IV-A of the Social Security Act says that State plans for Aid to Families with Dependent Children programs must provide methods of administration found by the Secretary to be necessary for the proper and efficient operation of the plans. In 1978 and

1982 GAO issued reports recommending that HHS require States to develop and incorporate into their management structure appropriate techniques and management controls to ensure efficient administration of the AFDC program. What steps have you taken to implement that recommendation?

Answer: Here are some of the things we are doing:

-- Our overall Performance Measurement initiative focuses State attention on issues of performance including individual employee performance, effective supervisory review and local agency monitoring.

-- Where we identify State practices which faciliate good employee performance, we encourage sharing of this information among States through technology transfers, conferences and the Welfare Management Institute (WMI) newsletter.

-- We have underway a contract to study the cost-effectiveness of corrective actions. Study results will help States evaluate the cost-effectiveness of correcting each type of error.

-- Monthly reporting, as mandated by the 1981 Omnibus Budget Reconciliation Act, is viewed as an orderly, business-like method for securing accurate, current information on each family and an efficient method of communication between the recipient and the public assistance agency. Experience in many States has proven that errors are prevented through regular reporting of circumstances and prompt follow-up of reported information. We have been providing in-depth guidance to States in both implementing and improving upon their monthly reporting systems.

-- We have issued to the States a compendium of error reduction techniques consisting of descriptions of successful error reduction practices in the seven highest error elements.

-- We have also provided guidance to States in developing their monthly reporting (MR) waivers. A monthly reporting waiver is granted, based on specified criteria, when a State can demonstrate that requiring certain types of cases to report monthly would not be cost effective. Since monthly reporting is considered an error reduction technique, States requesting MR waivers must also indicate what alternative management techniques will be used to ensure the eligibility and correctness of payment for those cases exempted from MR. Forty-one States have been granted MR waivers. We have underway a contract to evaulate the cost-effectiveness of categories of cases to be covered by monthly reporting.

-- We actively encourage States to use profiling to identify error prone cases. This statistical technique better targets case reviews, corrective action, and limited resources. We produced and distributed to all our regional offices a video tape on profiling, and we are developing an information package on profiling as a management tool.

-- Recognizing that effective interviewing for eligibility determinations can control fraud and abuse and reduce errors in AFDC, we have issued a catalogue of effective practices in the area of interview training.

-- We are developing a digest of State and local fraud control techniques.

-- The law permits HHS to provide incentive funding at the 90 percent rate of Federal financial participation to States for the design, development, and implementation of automated systems to administer the AFDC program. We have published a general systems design entitled the Family Assistance Management Information System (FAMIS) which can be used as a guideline by States in developing such systems. These systems employ various automated techniques to reduce errors and prevent fraud and abuse. They will standardize the eligibility determination process throughout a State, will automatically schedule redeterminations, will verify income and resource statements made by clients, will eliminate arithmetic errors in grant computation, and so on. Twenty-two States with approved Advanced Programming Documents (APD's) are currently developing systems, six more have submitted requests for incentive funding which are under review, and ten additional States are developing requests.

These are just a sample of actions being taken to encourage more efficient processing procedures in the AFDC program.

## STATE DIFFERENCES IN PRODUCTIVITY AND ADMINISTRATIVE COSTS

Question: GAO in a recent study found that wide differences in productivity exist among welfare offices processing AFDC claims. And your data on administrative cost per case and number of cases per worker show even wider productivity variances among States. Do you agree with GAO's finding that much of this difference is attributable to the fact that some States use streamlined case processing and automation while others do not?

Answer: While administrative cost per case and number of cases per worker, as reported, varies widely among States, the true differences may not be as extensive as reflected by this measure. We think these levels are affected by:

--Economic differences,

--Demographic differences;

--Workload differences, such as differences in volume and in case turnover rate;

--Differences in methods by which States allocate indirect costs among welfare programs;

--Differences in operations, e.g., streamlined case processing and automation, which may promote cost efficiency.

Because the numerous factors above are interrelated and have compound effects, statistical procedures cannot accurately delineate the proportional effect each factor has on the overall variance.

Question: In response to the GAO report you suggest that States have wide latitude to organize for and process claims as they see fit. But why should the Federal Government pay for administrative costs caused by inefficiencies in the way States process AFDC claims and why shouldn't States which improve productivity and hold down administrative costs, while maintaining or improving payment accuracy and timeliness, be rewarded for doing so?

Answer: We agree that the Federal Government should make every effort to encourage States to operate efficient programs. We currently do not have statutory authority to either reward or penalize States based on productivity or efficiency. However, we are continually looking at ways to better control administrative costs.

Question: GAO recommended that you establish a nationwide productivity measurement and reporting system to track and compare States' performance. Have you considered the feasibility of such a measurement system?

Answer: A contract to assess data used for performance indicators, including administrative cost per case, and to recommend new data resources, is nearing completion. A final contractor report providing the data assessment, recommendations, and cost estimates for implementing the recommendations is due shortly. After consideration of the contractor report we will develop, if feasible, a nationwide measurement and reporting system. We must disagree with GAO that most of the input/output data are already available. Apparently much of GAO's data are based on discussions, worker estimates, and observations, rather than hard data. While such methods are acceptable for auditing purposes, we must develop more objective data which will use consistent standards of measurement over time for managing the program.

Question: I understand that you have developed administrative costs per case, cases per worker and other performance indicators by State for AFDC. In addition, GAO has developed productivity measures for AFDC. You presently compare State error rates and set maximum levels. Couldn't you do the same for administrative costs?

Answer: We have taken the first steps in developing a mechanism to control costs by publishing annually the Profile of State Performance in AFDC which compares State administrative costs and which sets desired levels. We are currently studying the problems in comparability of State cost data.

Developing a proposal for an incentive/disincentive payment system based on AFDC performance would require the consideration of a number of issues and options including:

-- How to develop a balance between disincentives for poor performance and incentives for exemplary performance.

-- Whether to tie administrative cost performance to other measures of quality of service and payment accuracy in determining incentives/disincentives.

-- How to achieve and retain data integrity for administrative cost; especially, how to avoid allocation transfers between AFDC; Medicaid and Food Stamps that work against the integrity of the incentive/disincentive system. We have evidence to suggest that differences in allocation procedures among States significantly distort reported AFDC administrative cost.

-- Whether we should establish future cost caps in terms of specific targeted dollar amounts or retrospectively determine these caps based on a comparison of achieved levels of performance.

-- Whether we should develop a standard based on cost per case, cost as a percent of program cost, or a productivity standard.

-- Whether we develop multiple standards or adjustments to account for any regional differences in costs based on differences in demographics, economics and workload among States.

-- How to avoid penalizing States participating in special AFDC program activities which have an initial effect of increasing administrative costs yet are designed to reduce program outlays over time (FAMIS/work programs).

-- How to develop a productivity standard in conjunction with a cost standard, and how to obtain comparable and accurate productivity data.

ADP SYSTEMS FOR AFDC ADMINISTRATION

Question: You have developed a general ADP system design--the Family Assistance Management Information System (FAMIS)--which is to serve as a standard that States are to meet to be eligible for ADP incentives Federal matching funds. In a 1981 report, GAO recommended that HHS enhance the design of this system so that it can be used as an integrated system for processing AFDC, Medicaid, Food Stamp, and Social Service program activities. What have you done relative to this recommendation?

Answer: The FAMIS was originally designed in such a way that State agencies choosing to integrate the AFDC, Medicaid, Food Stamp and Social Service automated system functions could do so by implementing adaptations to the FAMIS design.

As a result of a Presidential initiative, the Office of Family Assistance (OFA) was asked by the Assistant Secretary for Managment and Budget (ASMB) to take the lead role in developing a Federal General System Design that addressed the integration of the automated system functions for the AFDC, Medicaid and Social Services Programs.

The product of that effort was made available to approximately 20 State welfare agencies with a request for comments. Most of the comments have been favorable and recognized the value of integrated systems in a State welfare agency environment. We are currently developing a final product.

## AFDC AND FOOD STAMP PROGRAMS

Question: What is the status of your guide to States on the allocation of administrative costs between AFDC and Food Stamps and other welfare programs administered at the local level. We understand this guide has been in final draft form since 1981.

Answer: The Department prepared a "Guide for State and Local Government Assistance Agencies/Departments - Procedures for the Preparation and Submission of Cost Allocation Plans" (CAP's) in November 1981. This guide was issued in draft form in December of 1981 to enable States/local governments to adhere to the Department's requirements. Many States are now using the guide to prepare their CAP's.

Based upon several tests conducted in our regions, the States are making significant progress in their compliance with the requirements.

Question: In a recent report GAO recommended formulating between the AFDC and Food Stamp programs uniform requirements for measuring applicant income and assets and common time periods for processing applications and closing cases. Have you begun working with the Food and Nutrition Service to standardize these requirements?

Answer: Yes. We have formed a task force consisting of staff from the SSA Office of Family Assistance and the Department of Agriculture's Food and Nutrition Service. The task force is working to identify policies and regulations which can be made compatible without statutory changes.

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## QUESTIONS SUBMITTED BY SENATOR LAWTON CHILES

Question: In its May 1982 report, GAO concluded that because of automated data processing complaints, the potential exists for major legislation affecting Social Security to preempt your efforts to modernize the computer system. What impact has implementation of the 1983 Social Security Amendments had on modernization? Have there been any specific projects affected? Has there been any effect on yearly cyclical software maintenance?

Answer: It is true that, in the past, major legislation affecting SSA has preempted efforts to modernize SSA's computer systems. In recognition of this, one of SSA's major objectives since beginning the SMP has been to establish an effective, SSA-wide ADP planning system. For the past 2 years SSA has developed a formal SSA-wide ADP plan which describes in detail what SSA will accomplish in its computer systems area each year. A similar plan for FY 1985 is scheduled for completion this summer. Under this plan, work has been categorized into major areas including:

- o Major Cyclical Workloads
- o New Legislation
- o SMP Activity
- o Maintenance of Current Systems
- o Short Term Improvements to Current Systems

Resources are allocated to the highest priorities first. New demands, such as legislation, can be carefully scheduled into the plan by reprogramming resources from lower priority activities. In essence, for the past 2 years we have been able to fully address SSA's cyclical, legislative and SMP initiatives while consciously limiting changes in the maintenance and short term improvement areas requested by users. As a result, we are successfully implementing work related to the 1983 Social Security amendments without any impact upon SMP projects or cyclical workloads. We have learned to manage our resources effectively so that our highest priorities are accomplished along with the most important of the short-term improvements.

Question: The May 1982 GAO report also identified barriers to hiring and retaining personnel with the skills needed to modernize Social Security's systems. What are you doing, and what more can be done, to attract and retain highly skilled personnel?

Answer: SSA has attempted to establish a well-rounded recruiting approach to attract skilled data processing personnel. SSA's recruiting activities involve several measures that address every level of the data processing community.

First, SSA has placed advertisments in selected newspapers for general recruiting or in support of SSA sponsored recruitment trips. These newspapers include the following: The New York Times, and the Washington Post, the Chicago Tribune, the Baltimore Sun, and Boston Globe and the Hartford Courant. Also, SSA has placed advertisements in several professional journals such as Computerworld and Information Systems News, as well as in minority publications.

In addition, SSA personnel from the Offices of Human Resources and Systems have participated in career fairs, job opportunity centers and minority conferences throughout the country. Cities in which we have participated in such recruitment efforts include: Atlanta, Georgia; Boston, Massachusetts; Detroit, Michigan; Pittsburgh, Pennsylvania; Chicago, Illinois; New York, New York; Dallas, Texas; Dayton, Ohio; Philadelphia, Pennsylvania; Washington, D.C.; Cleveland, Ohio; Anaheim, California; and Phoenix, Arizona.

Other steps have also been taken to fill entry level positions. For example, SSA personnel conducted recruitment interviews at approximately 40 universities, colleges and technical institutes. Also, SSA recently hired 34 computer programmer trainees from the Office of Personnel Management's (OPM) list of the Computer Specialist GS-5/7 Examination for entry level hiring.

As another step in its recruitment approach, SSA has prepared and distributed recruitment literature. SSA's publication, "Computers and People...The Right Combination for Social Security" has been distributed to colleges and minority and professional organizations in an effort to attract qualified data processing personnel.

Thus, advertising, participation in career fairs and conferences, interviewing at educational institutions, hiring and training entry level programmers based on an OPM examination, and preparing and distributing recruitment literature are all part of SSA's efforts to recruit skilled data processing personnel. In FY 1983, we hired 85 technical people via outside recruitment.

The primary barrier to attracting and retaining highly skilled data processing personnel is the salary structure we must work within. In addition, we find that the private sector is able to offer highly skilled systems technicians at salary levels comparable to GM 15 and SES salaries, but without the added responsibilities of supervision and management necessary at these levels within the Federal Government.

Question: What are the primary changes you've made to the original Systems Modernization Plan (SMP) as a result of the second annual plan revision process? Why were the changes made?

Answer: We have made changes in very few areas:

In the Data Communications Utility (DCU) Program, plans to install intelligent terminals in the field offices were revised. Under our software initiatives--primarily the modernization of the claims system--processing will reside wholly in the host processors in our central data center. This change also caused revisions in the hardware planned for the DCU, and therefore projects to replace some hardware were modified.

We also added a fifth program to the SMP; the Systems Operations Management Program (SOMP). The activities in the SOMP focus on updating the operation of our data center to the state-of-the-art. Included here are projects to automate the scheduling of our workloads on the computers to utilize fully the capacity of our new processors. Automating management of our storage media (magnetic tapes and direct access storage devices) and updating our systems software to fully utilize the technology our new hardware affords us are other key activities under the SOMP.

We decided not to replace the computer which processes administrative and management information workloads. Instead, we are defining management information requirements as we redesign our programmatic systems so that most management information will result as a by-product of programmatic processing on our main host computers.

The conversion of data files to direct access storage devices was accelerated. Data stored on disk not only would reduce our operational errors (attributable to the less reliable tape media, and to the need to manually handle tapes), but it also was essential to making significant improvements to our software and to transitioning to an on-line processing system.

We delayed plans to upgrade the processing environment in our program service centers. Early plans called primarily for replacements of hardware. Since then we have decided to reengineer the software as well and to install the more complete upgrade simultaneously. This redirection has minimal impact on the SMP.

The early plans to install customized, intelligent terminals in our field offices were abandoned in favor of using terminals which are standard in the industry. This approach not only is more economical, it also allows us to add on standard terminals under future competitive procurements, and to utilize standard, proven, industry telecommunications software.

Because of the poor state of some SSA software applications, we decided to accelerate redesigns of major subsystems of software. These include the Annual Wage Reporting System, National Debt Management System, Claims System, and Social Security Number Enumeration System.

Question: Given that all the planned tasks in any major computer modernization are not going to succeed initially, what have you learned during the first two years of SMP implementation?

Answer: While it is true that in any major computer modernization project planned tasks often do not succeed initially, fortunately the major planned tasks of the SMP have been successfully accomplished in its first 2 years. However, we have learned much, and adjusted appropriately. Some changes to tactical plans were made, primarily to accommodate changes in technical approach.

We learned that developing software under a disciplined set of standards and controls was difficult to institutionalize. We have issued the first version of the standards, the "Software Engineering Technology," and we are refining it incrementally. The software itself is in even worse condition than originally thought. Given the enormous size of most programs and the complex flow of transactions between them, even minor improvements to code are major undertakings. The software is less salvageable than originally presumed. Although we are proceeding to make many structural improvements to existing software, we have decided to invest more heavily in redesigning new software much earlier than originally planned. Expediting the schedule for developing new software will yield the maintainability, efficiency and highly automated functionality that will better serve the Agency's needs, sooner. We have also made a specific decision to integrate programmatic management information (MI) data requirements into the requirements for the new programmatic processing systems. Thus, some of the separate efforts originally aimed at MI software improvement have been replaced with plans for software redesign. These new directions will be reflected in the 1984 update of the SMP.

The actual operation of the computer data center was not originally foreseen as a major deficiency. We added a fifth program to the SMP to modernize operations and to upgrade the systems software the new computers would use so that their advanced technology could be fully utilized. And finally, we recognized that some improvements were needed to the existing systems to reduce cyclical workload backlogs, to reduce abnormal terminations of software due to data or logic errors, and to increase the rate of automation of several processes and improve accuracy and staff resource utilization. In the annual ADP planning process, the Agency sets aside some resources to concentrate on further critical operational improvements to assure that the existing system remains stable and responsive to the Agency's operational needs.

Question: In the May 1982 report, GAO concluded that the full scope of modernization--as described in the original SMP--will take 7 to 10 years rather than 5 years and will cost substantially more than Social Security's original projection of $478 million. Based on progress to date, what is your current estimate of 1) the total time to achieve the original, or modified goals of SMP? and 2) the total projected costs of systems modernization? (Please include all projects under the SMP plan, as well as other efforts to upgrade the system outside the formal Systems Modernization Plan.)

Answer: Systems modernization is an ongoing SSA priority. Continued modernization is needed to keep pace with technology and to improve SSA's business processes, especially with respect to taking advantage of advances in technology. Although the System Modernization Plan is an evolving plan, the major modernization activities spelled out in the original SMP are still projected to be accomplished within the original 5 years and within the originally estimated costs which totalled in the neighborhood of $500 million. Beyond the fifth year, our task will be to keep pace with the technology so SSA does not again fall behind.

## OFFICE OF REFUGEE RESETTLEMENT

### Questions Submitted by the Subcommittee

### THE LUNGREN AMENDMENT

Question: You are incorporating in the budget request the provision in the House-passed Refugee Assistance Extension Act mandating specific legal and financial responsibilities for voluntary agencies for refugees during the 90-day period after their admission, the so-called Lungren Amendment. This provision is controversial and has not yet been adopted by the Senate.

What are the Administration's reasons for supporting it?

Answer: The voluntary agencies have often claimed that immediate availability of welfare has prevented the agencies from working with refugees in securing employment soon after their arrival in the United States. This amendment would provide the agencies with ample opportunity to demonstrate that if the refugees are their exclusive responsibility and welfare is not accessible, then more refugees would find jobs and not use welfare. We also believe that the Lungren Amendment will help to clarify the responsibilities of the States and voluntary agencies and will provide the resettlement agencies with the opportunity to mount an intensive effort to get refugees into jobs and become self-supporting during their first 90 days.

Question: Why are you proposing short-circuiting the authorization process through appropriation bill language?

Answer: We are not proposing short-circuiting the authorization process. We support passage of the Lungren amendment and have accounted for this in the budget request. To assure the Congress is fully aware of this, we have included this in the appropriations bill language.

Question: If refugee legislation is not changed, how would you alter your budget request?

Answer: If refugee legislation is not changed, there would be no change in the FY 1985 budget request of $359,512,000 for Refugee and Entrant Assistance. However, the proposed $15,000,000 funds transfer to the State Department would not take place if the Lungren Amendment were not adopted.

## VOLUNTARY AGENCY EXPENSES

Question: According to the budget justification (P. 21), the Office of Refugee Resettlement (ORR) is allocating $15 million to the State Department for distribution to the voluntary agencies to enable them to meet refugee needs during their first 90 days in this country.

Do you believe this amount will cover all the voluntary agencies' new expenses?

Answer: The Department plans to allocate $15 million from the cash/medical/administration activity to the Department of State in order to implement the provisions of the Lungren Amendment. This amount is an estimate of ORR costs of reimbursing States for providing cash assistance to refugees during the initial 90-day resettlement period.

There will be no changes in the present procedure for reimbursing for medical assistance for refugees during the first 90 days.

These funds are not intended to cover basic needs of refugees, or for all refugees; they are to cover the estimated cash assistance payments that refugees are projected to receive during their first 90 days in the country. For this purpose, we believe the $15 million will be sufficient.

Question: Do you expect the House-passed refugee legislation to result in a cost saving due to a reduction in welfare dependency, and is this expectation reflected in the budget?

Answer: It is not possible at this point to forecast if the House-passed legislation will be the final version of reauthorization for the Refugee program. Therefore, we cannot predict whether cost savings and/or welfare dependency reduction would result and our budget request makes no assumption of savings.

## TARGETED ASSISTANCE AND SOCIAL SERVICES FUNDING

Question: Targeted Assistance and social services comprise the total budget to States to teach English, train, and place refugees into jobs. You are proposing to cut this budget in half in 1985 even though the three year population of refugees in the U.S. (which has formed the base for past allocations to States) drops less than 20%.

Please explain. Will this result in higher or prolonged welfare dependency?

Answer: The 1985 request includes a reduction for Targeted Assistance but the budget request for social services is slightly higher than the 1984 level.

The reduction in Targeted Assistance funding is based on the following:

-- Refugee admissions will have been down for the third straight year by 1985 and this special funding was created to deal with unanticipated high levels of refugee admissions.

-- By the end of 1984, over $160 million will have been made available in this account to assist communities to meet the special needs of refugees where there are high concentrations of refugees and entrants.

-- ORR has instituted other programs such as the favorable alternative sites program and the policy to resettle only family reunification cases in high impact areas that address this problem.

Also, ORR is currently examining changes in the program, on a demonstration basis, which would encourage States to assign refugees solely to an all Refugee Cash Assistance (RCA) program. This has the advantage of removing certain incentives to welfare use prevalent in the AFDC program as it operates in several key refugee States and permitting better management of the refugee caseload by linking refugees to those services which are likely to make them self-sufficient in a shorter period of time. Our data indicates that the RCA approach is generally more responsive to the employment needs of refugees.

Question: What services to refugees will be discontinued or reduced with the loss of these funds?

Answer: ORR does not feel that any services will be discontinued as a result of lower funding levels for social services in FY 1985. While level of support to some service categories will be reduced, we expect that these reductions will be consistent with a lowering of need for such services. Again, the impact of sustained social services funding over the past two years, as well as the results of Targeted Assistance, should justify the reductions proposed.

Question: According to an announcement in the February 13, 1984, Federal Register, you plan to reprogram more than $16 million in refugee appropriations from the Targeted Assistance activity to the Social Services activity.

Why wasn't the Appropriations Committee notified of this reprogramming proposal?

Answer: We do not believe that this action constitutes a reprogramming of funds because the use of Targeted Assistance for social services is authorized by the Immigration and Nationality Act (Section 412 (c) of P.L. 96-212).

Question: This Federal Register announcement covers only $60 million of the $125.9 million appropriated for refugee social services and Targeted Assistance. How will the remaining funds be used, and when will the money be released?

Answer: At the present time, the proposed allocation of the $81.5 million for Targeted Assistance is as follows:

ORR TARGETED ASSISTANCE FUNDING ($ in millions)

| | |
|---|---|
| TOTAL AVAILABLE FUNDS | $ 81.5 |
| ACTUAL/PLANNED COMMITMENTS | |
| Refugee and Entrant - Allocation by Formula | $ 40.0 |
| Social Services Activities | |
| Supplemental Funding for States | $ 17.0 |
| Funding for Mutual Assistance Associations (MAA's) | 3.0 |
| Total, Social Services | $ 20.0 |
| Dade County Education (Entrant Children) | $ 5.0 |
| Dade County (Entrant) Health Services | $ 6.0 |
| Targeted - Population Training Projects | $ 2.0 |
| Other Discretionary Projects | $ 2.1 |
| Preventive Health | $ 4.1 |
| Uncommitted Funds | $ 2.3* |
| TOTAL, TARGETED ASSISTANCE | $ 81.5 |

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* ORR is still undergoing internal review and discussion on use of these funds and expect to have decisions made shortly.

The FY 1984 social services funds are proposed to be allocated as follows:

| | |
|---|---|
| Allocation (to States) by formula | $ 40.0 million |
| Re-Allocation for population adjustment(s) | 2.2 million |
| ORR national discretionary projects | 2.2 million |
| Total, Social Services | $ 44.4 million |

ORR, through the end of the second quarter, FY 1984, has obligated $22.2 million in social services and $ 0 for Targeted Assistance. We propose to obligate funds for the balance of 1984 as follows:

| | 3rd Quarter | 4th Quarter |
|---|---|---|
| Social Services | $ 11.1 million | $ 11.1 million |
| Targeted Assistance | $ 35.0 million | $ 46.5 million |

## REDUCTION IN BUDGET REQUEST

Question: While the total refugee budget for 1985 decreases 30% from 1984 levels, including a decrease in State administration of 23%, why do Federal administration costs actually increase 2% and Federal positions drop by only 4%? Please explain.

Answer: ORR's overall FY 1985 budget request does reflect a 30% reduction from 1984 levels which may be explained by the reduction in the number of newly arriving refugees during FY 1985 and the significant reduction in the overall eligible refugee population receiving assistance in FY 1985 due to statutory as well as Federal limitations on the period of eligibility.

The State Administered Programs (one of five program activities requiring Federal administrative support) provide funds for cash and medical assistance and social services. State administrative costs under this activity are budgeted as a level (percentage) of those cash and medical program costs. The 23% decrease in FY 1985 for State administrative costs reflects the decrease in the refugee population expected to be served under this specific program due to reduced refugee flows into this country, a reduction in the base refugee population to be served due to 18 month and 36 month periods of eligibility and the increasing national trend of decreasing refugee welfare dependency.

Federal Administration under the Refugee program supports five separate program activities for refugee assistance: State Administered Programs, Targeted Assistance, Voluntary Agency Programs, Education Assistance for Children and Preventive Health programs. The Federal activity includes a comprehensive program and fiscal monitoring of all refugee assistance activities necessary for effective program management, the development, implementation and interpretation of Federal regulation, policies and guidelines and the ongoing development and analysis of new national initiatives to address the specific problems of refugee domestic resettlement.

The FY 1985 increase of 2% in Federal Administrative costs is a result of the January 1984 cost-of-living increase of 3-1/2% for salaries and inflationary factors affecting ORR's costs for telecommunication services, space, travel, etc.

## REFUGEE WELFARE DEPENDENCY

Question: What is the current refugee welfare dependency rate on a nationwide basis?

Answer: As of September 30, 1983, the end of FY 1983, the estimated welfare dependency rate of time-eligible refugees (that is, those refugees in this country 3 years or less) was about 57%.

Question: What specific steps are being taken to reduce welfare dependency?

Answer: Reduction of welfare dependency rates has been a major objective of the program over the last few years. Some of the initiatives taken by ORR during this period include:

- o Emphasis on employment - related activities in the Social Services and Targeted Assistance programs. The purpose of this initiative is to secure early employment for refugees and to avoid long-term welfare dependency.
- o Targeted Population Training Projects which encourage the use of mutual assistance associations to facilitate settlement and employment in local communities and to minimize secondary migration which after leads to extended welfare dependency.
- o Favorable Sites Initiative which attempts to locate new refugees in communities with a high potential for refugee employment.

As discussed earlier, the Administration also supports passage of the Lungren Amendment, which would make voluntary agencies responsible for refugees during the first 90 days. We believe that this approach would have the effect of avoiding early dependency on the welfare system.

Finally, ORR is also actively examining program changes that would encourage States to adopt an all-RCA approach to dealing with their dependent refugee caseload, particularly new encounters to the welfare system.

If widely adopted, this approach would eliminate disincentives of the AFDC program (e.g., 100-hour rule) and assure that refugees be provided ORR funded services which are likely to accelerate their entry into employment.

ORR's data show a national dependency rate of 57%; but when California is excluded from this calculation, the dependency rate is about 35%. Our data further show that States having predominantly RCA caseloads do a substantially better job of moving refugees into employment within a shorter period of time. ORR evaluation data also show that refugee use of welfare is generally not that prolonged except in California. If California will work with ORR in implementing certain changes in the system (adoption of a RCA model for AFDC caseloads), the prospects of less use of welfare for long periods of time are improved. ORR is committed to taking measures which permit States and voluntary agencies to work more effectively with refugees to avoid the use of welfare except as transitional assistance for relatively short periods of time.

Question: Do you lack legislative authority to do more?

Answer: The ability of ORR to prevent refugees from accessing welfare is largely constrained by how voluntary resettlement agencies provide sufficient services and support under the reception and placement grants to keep refugees off welfare. Therefore, the Administration is supporting both the Lungren Amendment to the Refugee Assistance Extension Act of 1983 (which makes voluntary agencies legally and financially responsible for the basic needs of refugees during the first 90 days after entry into this country) and the Fish Amendment to the same legislation (which would direct the Secretary of HHS to develop and implement alternative projects for refugees, who have been in the United States less than 18 months, in a manner that encourages self-sufficiency and reduces welfare dependence). With the passage of the Lungren and Fish Amendments along with refugee-related legislation currently on the books, we believe we have sufficient authority to continue to pursue efforts to reduce refugee dependence on cash assistance.

## SOCIAL SERVICES FUNDS ALLOCATION

Question: Over the last few years the Department has allocated social service funds to States on the basis of the number of refugees in the United States less than three years. The Department has indicated its belief that this was a programmatically sound criterion and that the States were generally supportive.

Why then is the Department cutting this criterion in half in 1985, to base allocations on refugees in the United States under 18 months?

Answer: The budget does not propose to change the allocation formula used for distributing social services funding. In FY 1985, as in previous years, these funds will continue to be distributed on the basis of the number of refugees in the United States for three years or less.

However, the 1985 budget request for social services is based on the estimated 18-month refugee population.

This reference point is used for budget formulation purposes because the need for social services is much greater for this group than for other refugees, many of whom are able to find employment and no longer require assistance.

## THE LUNGREN AMENDMENT

Question: How much money do you expect to save by turning the first 90 days of refugee assistance over to voluntary agencies?

Answer: The Office of Refugee Resettlement's FY 1985 budget request supports the passage of Section 4 of H.R. 3729, as passed by the House of Representatives on November 14, 1983. This section of the Refugee Reauthorization Bill is commonly referred to as the Lungren Amendment.

This amendment requires voluntary resettlement agencies to be legally and financially responsible for meeting the basic needs for food, clothing and shelter, and for transportation to interviews of each refugee resettled during the 90-day period beginning with the date the refugee was admitted to the United States.

The Department plans to allocate $15 million from the cash/medical/administration activity to the Department of State in order to implement this policy. This amount is an estimate of ORR costs of reimbursing States for providing cash assistance to refugees during the initial 90-day resettlement period.

There will be no changes in the present procedure for reimbursing for medical assistance for refugees during the first 90 days.

The FY 1985 budget has not assumed any cost savings as a result of the Lungren Amendment, since it is not yet enacted and there is no data on its impact on the Refugee program at this time.

Question: What assurances can you give that refugees will not be adversely affected by this policy change?

Answer: As mentioned earlier, with the passage of the Lungren Amendment, the Department will transfer $15 million to the Department of State to provide voluntary agencies with additional resources to assist refugees during the initial 90-day period. These funds, augmented by the private resources that the agencies traditionally contribute to assist refugees under the reception and placement grants, should be adequate to obviate the need for refugees to use welfare. States will be obliged to ascertain from the refugee and his/her sponsor that insufficient resources are available to the refugee before making a determination that the refugee is eligible for welfare. If the agencies use the resources available, the indications are that the refugee will be adequately supported by the agency. In addition, in those instances when a refugee might move to a new locality where the voluntary agency is not represented and finds himself in need, we would plan to reimburse States for assistance provided to a refugee during his first 90 days.

## REFUGEE EDUCATION ASSISTANCE

Question: You are proposing to cut education assistance for refugee children from $16,600,000 in fiscal 1984 down to $12,976,000 in fiscal 1985. This activity was funded at $44,268,000 in fiscal 1981.

What evidence do you have of a declining need to compensate local educational agencies for the extraordinary costs of educating refugee children?

Answer: In FY 1983, 39,167 Southeast Asian refugees arrived in the United States, approximately 25,000 fewer than the admissions ceiling of 64,000 established during the consultation process. This compares with the FY 1982 admission figures for Southeast Asians when 72,155 such refugees were admitted. Thus, FY 1983 arrivals represent a 46 percent reduction from the 1982 level of admissions.

At the end of FY 1983, the median age of the resident Southeast Asian population was 23.5, without a significant age difference between men and women. The school age population (6-17) of refugee children was about 29 percent of the total; whereas in FY 1982, it was approximately 32 percent.

Since FY 1980, approximately $135 million has been appropriated for this transitional education assistance program needed to meet the needs of refugee children. Therefore, given the reduced refugee flows and the capacity already established to meet the special needs of refugee children, this activity is budgeted at the $13 million funding level in FY 1985.

Question: Why have you chosen to base your budget request on a formula which emphasizes the number of refugee children arrivals during the last two years, when heavily impacted school systems bear the burden for 12 years?

Answer: The regulatory formula for the Transition Program for Refugee Children, the supplemental educational assistance funding provide to State educational agencies and local educational agencies for refugee children, was promulgated in the Federal Register on January 14, 1981. Public comments at that time reflected recognition that recent refugee arrivals have greater educational needs which generate additional costs. Public reaction to that concern generally remains the same today.

1984 TARGETED ASSISTANCE

Question: Provide for the record a detailed spending plan for the $81,500,000 Targeted Assistance funding for Fiscal 1984.

Answer: At the present time, the proposed allocation of the $81.5 million for Targeted Assistance is as follows:

ORR TARGETED ASSISTANCE FUNDING ($ in millions)

| | |
|---|---|
| TOTAL AVAILABLE FUNDS | $ 81.5 |
| ACTUAL/PLANNED COMMITMENTS | |
| Refugee and Entrant - Allocation by Formula | $ 40.0 |
| Social Services Activities | |
| Supplemental Funding for States | $ 17.0 |
| Funding for Mutual Assistance Associations (MAA's) | 3.0 |
| Total, Social Services | $ 20.0 |
| Dade County Education (Entrant Children) | $ 5.0 |
| Dade County (Entrant) Health Services | $ 6.0 |
| Targeted - Population Training Projects | $ 2.0 |
| Other Discretionary Projects | $ 2.1 |

| | |
|---|---|
| Preventive Health | $ 4.1 |
| Uncommitted Funds | $ 2.3* |
| TOTAL, TARGETED ASSISTANCE | $ 81.5 |

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* ORR is still undergoing internal review and discussion on use of these funds and expect to have decisions made shortly.

## REFUGEE REPROGRAMMING

Question: Do you intend to reprogram funds between line items in the fiscal 1984 refugee Appropriation?

Answer: As set forth earlier, the Office of Refugee Resettlement does not believe that any reprogramming of Refugee funds is taking place in 1984.

Question: If so, when do you plan to submit a reprogramming request to this committee?

Answer: As stated above, we have no such plans.

## TARGETED ASSISTANCE FUNDING

Question: What criteria were used to reduce your Targeted Assistance request by 75 percent from 1984 to 1985?

Answer: The President's FY 1984 budget for targeted assistance was $35.0 million. Because the Refugee program is not authorized for FY 1984, it is currently operating under provisions of the FY 1984 Continuing Resolution (CR), which authorizes funding for activities at the current rate of operations. Therefore, as a result of the CR, the FY 1984 budget level of targeted assistance is $81.5 million. The FY 1985 budget request for the activity is $19.4 million.

The reduction in Targeted Assistance funding in FY 1985 (from the FY 1984 budget level) is explained by the facts that:

-- Refugee admissions will have been down for the third straight year by 1985 and this special funding was created to deal with unanticipated high levels of refugee admissions.

-- By the end of 1984, over $160 million will have been made available in this account to assist communities to meet the special needs of refugees where there are high concentrations of refugees and entrants.

-- ORR has instituted other programs such as the favorable alternative sites program and the policy to resettle only family reunification cases in high impact areas that address this problem.

It is for the very reasons that there will have been substantial funding under Targeted Assistance that we feel confident that this lower level of funding is sufficient in FY 1985. Targeted

Assistance is precisely that - an allocation of funds to certain areas for a limited period of time, the purpose of which is to target services on refugees having serious difficulty in achieving self-sufficiency.

Question: Is there evidence that additional funding is not needed?

Answer: Since most Targeted Assistance projects did not become operational until FY 1984, firm results are not yet available. Also, many localities have undertaken creative projects which are designed to deal with more difficult cases, and more time will be needed for these projects to take effect. ORR will, however, be measuring the effectiveness of these projects. There is the prospect from preliminary information available, as well as the performance claims made by counties for their projects, that a major segment of the more difficult refugee caseload will be helped and that continued high levels of Targeted Assistance aid will not be required.

## PREVENTIVE HEALTH

Question: Why is the preventive health budget being doubled in 1985?

Answer: In 1984, approximately $4.4 million will be available for the Preventive Health program under the Continuing Resolution. In addition, ORR plans to make $4.1 million of Targeted Assistance funds available to States for preventive health activities. As a result, a total of approximately $8.5 million will be available for preventive health activities in 1984, or about $400,000 less than the amount requested for 1985.

Question: Have these efforts been inadequate in prior years?

Answer: As indicated earlier, when total resources available for preventive health activities are considered, we do not believe that the level of effort in prior years has been inadequate. At the 1985 request level, 85% of arriving refugees (other than those being resettled under the matching-grant program) will be provided domestic health assessments, 30% of the total number of health assessments will be provided to secondary migrants, and up to 70% of the refugees who have tuberculosis infections and are eligible for preventive therapy will be started on treatment. Technical assistance for refugee tuberculosis control measures will also be provided.

The FY 1985 request also includes support for the continuation of the monitoring of overseas medical processing of refugees from Southeast Asia. Furthermore, $637,000 is requested to improve the monitoring of the medical screening and medical documentation system for non-Indochinese refugees arriving from European, African and Western Asian locations. Without these additional funds, the quality of the medical examinations done overseas cannot be assured and local health departments will continue to receive incomplete and often erroneous medical information about refugees arriving from these regions.

## REFUGEE 18-MONTH POLICY

Question: Now that the policy to reduce assistance to 18 months for refugees not categorically eligible for other programs has been in effect for two years, what is your assessment of the effects?

Answer: As indicated in a report prepared for the Department by Urban Systems Research and Engineering, the implementation of the changes had three institutional effects. First, it necessitated changes in the State refugee programs. These changes caused an initial overload on program resources, but not clear long-term problems after the transition was made. Second, there were some effects on the mainstream assistance programs (AFDC and Medicaid). During the transition these effects involved ripples from the refugee program and the need to provide back-up support. Longer term effects seem negligible. Third, and most serious, was the impact on State and local General Assistance (GA) programs. The lack of interrelationships between the Federal welfare system and such GA programs was the major problem. Longer term effects are less visible and disruptive. Overall, we consider that the effects were not overly serious, though the speed of implementation caused disruptions we would rather have avoided.

Question: What have the cost savings been?

Answer: The net program savings resulting from this policy change are exceedingly difficult to estimate. Had there been no change, many refugees would have continued to receive refugee cash assistance and thus made refugee program costs higher than they currently are. However, some of these same refugees might have been removed from cash assistance rolls in any case. The situation is further complicated by the recession at the time which made employment a more difficult prospect, and by shifting characteristics of refugees arriving in 1980 and 1981 who were the ones affected by the original change of policy in 1982.

Question: What effect did this have on refugee employment, migration, family disruption?

Answer: There has been a great deal of anecdotal information on the effects of the policy changes on refugee employment patterns, migration, and family disruption. It is clear that there was initial disruption of many refugees' lives, and over the longer-term refugees in almost all States face more limited availability of public assistance. The secondary migration of significant numbers of refugees, particularly those from Highland Laos, has also been documented.

While national data on employment patterns and family composition are not available, separate studies conducted in Oregon and Washington -- States where the effects of the policy changes were particularly severe -- provide illustrative information. In Washington State, a post-termination survey found that two-fifths of those terminated had found jobs of some kind, and about one-fifth had moved out of state. Of those who moved, about one-half had gone to California. The information from Oregon provides somewhat different insights, partially reflecting methodological differences. By the end of 1982 there was no noticeable improvement in the general employment situation of refugees, many of the Highland Laotian groups had moved away, and there were at least a few family breakups. However, the major changes appeared to be aggregation into larger family units, and a more eclectic use of resources, particularly gardening, to make ends meet.

## ASSIMILATION OF REFUGEES

Question: How many refugees who have been here over three years are receiving assistance in AFDC General Assistance programs around the country?

Answer: According to findings from ORR's October 1983 annual survey of Southeast Asian refugees, 32 percent of those households with refugees who have lived in the United States more than three years were receiving some form of cash assistance. No detail is available on the type of cash assistance (AFDC, general assistance, or SSI) being used by time-expired refugees, since records are not kept in most States on time-expired refugees. A June 1983 California study, however, showed that of 25,068 time-expired cases, 20,735 were receiving AFDC and 4,333 were receiving general assistance.

Question: In other words, what proportion of the refugees don't financially assimilate within three years of arrival?

Answer: An October 1983 survey showed that 32% of the Southeast Asian refugees who had entered the United States before 1983 and had been in the country more than three years lived in households receiving cash assistance.

## THE LUNGREN AMENDMENT

Question: What is the Department's rationale for supporting the proposed policy to make voluntary agencies financially and legally responsible for refugees during the first 90 days?

Answer: The distinction between the responsibilities of the voluntary agencies and those of the public welfare agencies is often unclear, and the vast majority of refugees are going on cash assistance soon after their arrival. We believe that the Lungren Amendment will help to clarify responsibilities and will provide the resettlement agencies with the opportunity to mount an intensive effort to get refugees into jobs and become self-supporting during their first 90 days.

Question: If welfare dependency of refugees is still over 50%, won't most refugees simply become dependent three months later than otherwise and perhaps lose three months of English and other employment and training services?

Answer: The Department believes that the $15,000,000 in funds to be transferred to the voluntary agencies will enable the agencies to provide expanded assistance to refugees and enhance the ability of refugees to find employment before they become dependent on welfare. Since nearly all refugees who access welfare do so within their first 90 days in the United States, it is expected that this policy will divert refugees from early access to welfare and subsequently long-term welfare dependency. By providing initial assistance to refugees through the voluntary agencies rather than through the welfare systems, we are confident that voluntary agencies will meet the challenge of helping refugees become self-sufficient as soon as possible.

Question: How did the Department arrive at the $15,000,000 figure to be transferred to the voluntary agencies for this initiative?

Answer: The $15.0 million estimate of funds to be transferred is based on the 72,000 estimated refugee arrivals in FY 1985, the projected welfare (cash assistance) dependency rate during the first 90 days in the country and unit costs for cash assistance for that 90-day period, plus anticipated related administrative costs now borne by the States and localities.

## MAINTAINING VOLUNTARY AGENCIES

Question: Does the Department intend to reimburse States for costs of refugees who become eligible for cash assistance during the first 90 days after arrival in the United States through migration or other circumstances? If not, how does the Department propose to make refugees ineligible during this period or handle the lawsuits and complaints from States?

Answer: We propose to continue to reimburse States for any assistance costs which may occur during a refugee's first 90 days since there may be individual cases where the refugee's sponsoring voluntary agency is not represented and he finds himself in emergency circumstances. We also believe that the provision of assistance through the voluntary agencies, under the Lungren Amendment, would obviate almost completely any need for public assistance during the 90-day period.

Question: Will the State Department have sole responsibility for monitoring the voluntary agencies' compliance with these new obligations, or will this responsibility be shared with the Office of Refugee Resettlement (ORR)? What will be your role?

Answer: The Department of Health and Human Services must defer to the Department of State regarding the specifics of how the mandate of the Lungren Amendment will be implemented. The State Department enters into agreements with the voluntary resettlement agencies concerning the nature of their responsibilities under the refugee program and also furnishes Federal funds to the agencies. The 1985 HHS budget includes $15 million for transfer to the Department of State for its use in funding the voluntary agencies to carry out this provision.

Question: Are refugees who do not receive some form of refugee cash and medical assistance eligible for refugee social services in all States?

Answer: Yes, the 36-month limit of ORR reimbursement for refugee cash and medical assistance does not apply to the provision of social services. Nor is cash and medical entitlement a prerequisite to receiving social services. Such services may be provided to any refugee; however, States prioritize refugee client groups to be served and understandably focus services on new arrivals and other dependent refugees in order to channel them into employment and reduce utilization of public assistance. Likewise, targeted assistance funds may be used for any refugee whose economic needs are such that additional employment services would either free the refugee from public assistance or from a state of unemployment or underemployment.

## MATCHING GRANT PROGRAM

Question: To what extent do you monitor the performance of voluntary agencies participating in the matching grant program?

Answer: In FY 1984, after consultation with the voluntary agencies, ORR issued new guidelines for the Matching Grant Program which, by specifically stating the length and scope of services to be provided, strengthen our ability to monitor agency performance. Included as part of the evaluation criteria for funding applicants is the adequacy of the national agency's plan for monitoring the services provided by its affiliates. ORR program staff have continued to systematically monitor performance to the extent possible through, among other means, review of agency progress reports.

Question: What percentage of refugees assisted through the voluntary agency matching grant program also receive public assistance?

Answer: Since provision of maintenance support through the Matching Grant Program has not previously been required and since services provided through the program vary, we do not have meaningful data on this question. The Office of Refugee Resettlement's new program guidelines require that agencies provide maintenance support for refugees for up to three months, as necessary, after the initial month's support provided through the State Department's Reception and Placement Cooperative Agreement.

## REFUGEE PLACEMENT POLICY

Question: In December, the Office of Refugee Resettlement proposed the designation of certain areas as impacted for the purposes of the placement of refugees. Such areas would be recommended as unavailable for the resettlement of refugees, except in the case of immediate family reunification.

What proportion of new refugee entries are family reunification cases?

Answer: The Bureau for Refugee Programs in the Department of State has provided the following information. During the first two quarters of FY 1984, 61 percent (or 4,242 out of 7,011) of the Southeast Asian refugees for whom assurances were provided by the voluntary agencies were family reunification cases as defined in the 1982 Refugee Assistance Amendments.

About 23 percent (1,642) had other relatives or friends in the United States and about 15 percent (1,077) were free cases. Of the non-Southeast Asian assurances provided during February 1 - March 31 of this year (data were available on these groups only for this period), 28 percent (110 of 387) were family reunification cases, 22 percent had other relatives or friends in the United States, and 49 percent (191) were free cases.

Question: What comments have you received on this proposal?

Answer: The Department has received 114 comments on the Notice of Proposed Rule-Making and accompanying Proposed Designation of Impacted Areas, published in the Federal Register on December 12, 1983. Comments were submitted by State governments, county governments, local civic groups and forums, voluntary agencies, service providers, churches, refugee groups, individual refugees and other interested individuals, as well as from members of Congress.

The comments generally contained more than one issue or subject. These are listed as follows, in order of frequency: (1) The data base used in the impact calculations was not current; (2) the proposal will encourage secondary migration and therefore cause hardship on refugees or create service problems due to inability to determine where to allocate funds: (3) definition of family is not culturally sensitive, and therefore, not supportive of effective resettlement--it would lead to secondary migration or defeat the humanitarian purpose of the refugee program; (4) the policy should not be applied to all ethnic groups, since only some have arrived in sufficient numbers to create impact; (5) the waiver process was not fully explained and it is feared that it would be too cumbersome or unresponsive; and (6) the proposal, using population and assistance data, does not accurately reflect the true resettlement and impact situation, and it should only be part of a process of local determination of impact, not Federal.

Question: When do you plan to implement it?

Answer: Because of the importance of this proposal and the strong comments received on all sides of the issues, ORR has included placement policy as an agenda item for its Regional Consultations being held during the Spring of 1984. This allows further open discussion of views and problems and the direct exchange of ideas among various interested parties. After the last consultation, which occurs in April, ORR will prepare the final proposal.

Question: Do you expect it to result in a cost saving?

Answer: Because the policy would reduce placement of refugees in areas which present limited opportunity for early self-sufficiency, we do expect that it would produce some savings to the program overall. However, the effects of implementing the policy are expected to vary according to the numbers of arrivals, admissions priorities, ethnicity and family reunion, and domestic program operations. Therefore, the amount of cost savings cannot be accurately estimated at the present time.

Question: How do you propose to control secondary migration to areas designed as impacted?

Answer: Refugees are, of course, free to move about the country as are citizens and other residents. The placement policy itself would not address possible refugee movement after initial placement. However, ORR has already taken and will continue to take steps to reduce the incentives which may cause refugees to move to impacted areas.

For example, ORR has provided targeted assistance funds to refugee self-help groups to enhance employment opportunities by making available specially-adapted technical assistance and services in communities where refugees now live. The FY 1983 Highland Lao initiative is one illustration of this strategy. Secondly, ORR is awarding targeted assistance funds to States facing significant reductions in FY 1984 social service funding. This is being done to maintain program continuity and remove the perception by refugees living in the State that their services are to be eliminated. Thus refugees are receiving the message that they should seek to become self-sufficient in the community where they currently reside. These measures do not, of course, guarantee that refugees will not migrate to impacted areas, but we believe that they are responsible and appropriate programmatic strategies for addressing this important concern.

## REFUGEE EDUCATION ASSISTANCE

Question: According to the budget justification (p. 25), you are requesting budget authority of approximately $13 million for the education of Refugee and Cuban/Haitian Entrant children for Fiscal 1985, which you indicated is a reduction of approximately $3.6 million from the Fiscal 1984 budget authority of $16.6 million. However, during Fiscal 1984, ORR made approximately $16.6 million available for the education of refugee children and an additional $5 million available for the education of Entrant children, totaling approximately $21.6 million. Thus, the reduction proposed is closer to $8.6 million or approximately a 40 percent reduction from Fiscal 1984.

Why has the request for funding declined so sharply?

Answer: The FY 1985 budget request for Children Education Assistance is about $13.0 million. It was formulated on the basis of the estimated numbers of school age children who would arrive in this country as part of the total anticipated admissions ceiling of 72,000 in 1985. No entrants are projected to be admitted into the United States in 1985, therefore, there was no budget for entrant children in 1985. The budget request of $13.0 million was based on estimated 1985 refugee children arrivals.

Question: How will this affect the amount of funding available per student?

Answer: As indicated earlier, refugee admissions are down, and therefore, the refugee school age children population is also down. Likewise, the Cuban/Haitian Entrant school age population is almost non-existent since a majority of those children are older and now are out of the school system. Thus, the impact on available funding per student will be minimal, if any.

The Department of Education will use the same methodology for distribution of funding to State and local education agencies for FY 1985, that was utilized in FY 1984.

That formula places the greatest emphasis on the number of refugee children who are recent arrivals and require more immediate and special educational assistance. Secondary level refugee children receive even more formula emphasis because of their known difficulties in learning at an older age.

Funding under the Transition Program is estimated at approximately $291 of assistance per eligible student in FY 1985, compared with an estimated figure of $282 for this current fiscal year. However, the approximate amount of funds available per eligible student may increase or decrease depending on the total number of eligible students that the States report in their official "child count".

Question: You indicate that approximately $135 million has been appropriated for the development of special curriculum materials for refugee children since fiscal 1980.

Could you specify the funding sources and amounts for each of the fiscal years?

Answer: Since 1980, under authority of the Refugee Act, the annual budget for Refugee and Entrant Assistance has specifically included a line item for Refugee Education Assistance for Children. The final appropriations for this activity, by fiscal year, since 1980 are:

| | |
|---|---|
| FY 1980 | $ 23.2 million |
| FY 1981 | 44.3 million |
| FY 1982 | 22.7 million |
| FY 1983 | 16.6 million |
| FY 1984 | 16.6 million |
| FY 1985 (request) | 13.0 million |
| Total | $ 136.4 million |

In addition, under authority of the Refugee Education Assistance Act of 1980, a similiar program activity has been funded for entrant children. Since 1981, including projected 1984 obligations for the program, over $20.0 million will have been appropriated for entrant children education assistance.

Question: Many States have been receiving funds for the education of refugee and/or entrant children since 1980.

Have these States developed mechanisms to meet the special education needs of these children, e.g., special materials and supplies, special curriculum? How are funds allocated to these States in FY 1985 to be used?

Answer: The American Institutes for Research in the Behavioral Sciences, Palo Alto, California, conducted an "Evaluability Assessment of Transition Program for Refugee Children" in late FY 1982, for the Department of Education which discussed, among other issues, State mechanisms developed to help refugee children.

This assessment report states: (1) appropriate materials and techniques for educating refugee children are being developed, adapted, and used; (2) promising practices and products are being developed at the local level; (3) training materials and techniques are available and school personnel are learning from actual experience; and (4) some formal mechanisms are in place to help refugee parents and family members succeed.

Overall, the needs of recent refugee student arrivals remain constant, therefore, the allowable supplemental education activities remain the same. Those activities include: tests to determine educational needs of children; educational services with emphasis on instruction to improve English language skills; bilingual education; remedial programs; in-service training for parents; and school counseling and guidance services. An amount equal to one percent of a State educational agency's funding allocation is allowed for State administrative costs, and 15 percent of each local educational agency's allocation can be used for support services.

## TARGETED ASSISTANCE AND SOCIAL SERVICES

Question: Was the social service budget for 1984 decreased by $27 million from 1983 simply because of the Targeted Assistance allocation or were there other reasons?

Answer: Since the Refugee program currently is not authorized by law, it is operating under authority of the 1984 Continuing Resolution (Public Law 98-151). In most cases, the current rate under a Continuing Resolution (CR) has been defined as the same funding level as appropriated in the previous year. However, because some of the ORR activities are clearly tied to refugee admissions, the CR level for Social Services was calculated to take into account the continuing decline in refugee admissions and eligible population. This change from the 1983 enacted level is based on Decision B-197636 issued by the Comptroller General on February 25, 1980 that permitted HHS to raise the CR level over the previous year's appropriation due to increased refugee admissions.

Based on that interpretation, for social services, we have determined that the Continuing Resolution level is $44.4 million. This is a reduction of $27.3 million from 1983.

The basic difference between the 1984 Continuing Resolution and the 1983 appropriation is admission levels used in calculating funds for this activity. Actual admissions in 1983 were 59,300 instead of the 86,000 originally assumed. In 1984, the consultation level of 68,000 has been discounted by 15 percent based on the fact that in recent years, actual admissions have been running about 30 percent lower than the consultation level.

Under the same assumptions used in formulating the 1983 President's budget, the 1984 funding level is $32 million.

Since the Congress appropriated $12.4 million more than the 1983 President's budget request ($71.7 million as opposed to $59.3 million), $12.4 million was added to the $32 million for the total of $44.4 million.

Question: It appears that the Department does not consider $44,400,000 to be an adequate level of social services funding since it is shifting $20,000,000 of Targeted Assistance funds to its State social service allocations for 1984.

In light of this, why is the 1985 social service budget only 1% greater than the 1984 line item and $18,000,000 less than proposed 1984 State allocations?

Answer: In 1984, Social Services funds were augmented by Targeted Assistance funds in order to avoid serious disruption of social services projects initiated in 1983. However, we do not believe that continuing social services funding at the 1983 level is justified in the future because of the steady decline in the level of refugee admissions over the last three years and because we expect programs which began in 1984 and previous years to result in a greater degree of self-sufficiency among refugees and a reduced need for social services.

## TARGETED ASSISTANCE ALLOCATIONS

Question: Provide for the record the breakdown of Targeted Assistance funding for each of fiscal years 1983 and 1984, by State and county. Include your current plan for all available fiscal year 1984 Targeted Assistance funding.

Answer: The information is as follows:

ORR TARGETED ASSISTANCE FUNDING ($ in millions)

| | FY 1983 | FY 1984 |
|---|---|---|
| TOTAL AVAILABLE FUNDS | $ 81.5 | $ 81.5 |
| ACTUAL/PLANNED COMMITMENTS | | |
| Refugee and Entrant - Allocation by Formula | $ 58.9 | $ 40.0 |
| Social Services Activities | | |
| Critical Unmet Needs | $ 7.0 | -- |
| Supplemental Funding for States | -- | $ 17.0 |
| Funding for Mutual Assistance Associations (MAA's) | -- | 3.0 |
| Total, Social Services | $ 7.0 | $ 20.0 |
| Dade County Education (Entrant Children) | $ 5.0 | $ 5.0 |
| Dade County (Entrant) Health Services | $ 6.0 | $ 6.0 |
| Targeted - Population Training Projects | $ 4.1 | $ 2.0 |
| Other Discretionary Projects | $ -- | $ 2.1 |
| Preventive Health | $ -- | $ 4.1 |
| Uncommitted Funds | $ .5* | $ 2.3** |
| TOTAL, TARGETED ASSISTANCE | $ 81.5 | $ 81.5 |

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* Of this amount, $.2 million had been announced for Illinois (Cook County) for Entrant Targeted Assistance. However, the State did not apply for those funds, so that amount was not obligated and became uncommitted.

** ORR is still undergoing internal review and discussion on use of these funds and expect to have decisions made shortly.

Of the $81.5 million in FY 1983, $58.9 million was allocated by formula to impacted counties. The equivalent amount in FY 1984 is $40.0 million. The actual and estimated award for each county is:

## TARGETED ASSISTANCE ALLOCATIONS

### Counties for Targeted Assistance Program and Allocation - FY 1983-1984

| County, State | FY 1983 - Total Award | FY 1984 Proposed Allocation |
|---|---|---|
| Alameda, CA | $ 1,483,669 | $ 987,211 |
| Contra Costa, CA | 424,217 | 282,268 |
| Fresno, CA | 819,219 | 545,137 |
| Los Angeles, CA | 7,492,324 | 4,985,278 |
| Merced, CA | - | 665,385 |
| Orange, CA | 3,333,843 | 2,218,288 |
| Riverside/San Bernardino, CA | 423,226 | 281,608 |
| Sacramento, CA | 1,269,875 | 844,955 |
| San Diego, CA | 2,484,814 | 1,653,357 |
| San Francisco, CA | 1,850,372 | 1,231,209 |
| San Joaquin, CA | 1,281,378 | 852,609 |
| Santa Clara, CA | 2,481,839 | 1,651,378 |
| Stanislaus, CA | 231,842 | 154,264 |
| Denver, CO | 500,518 | 333,037 |
| Washington D.C. | 54,738 | 36,422 |
| Dade/Broward, FL | 15,290,500 | 10,174,066 |
| Hillsboro, FL | 261,618 | 174,077 |
| Palm Beach, FL | 345,833 | 230,112 |
| Honolulu, HI | 551,152 | 366,728 |
| Cook/Kane, IL | 2,358,440 | 1,722,678 |
| Sedgwick, KS | 540,500 | 359,640 |
| Wyandotte, KS | 76,452 | - |
| Orleans, LA | 420,836 | 280,438 |
| Montgomery/Prince Georges, MD | 512,735 | 341,166 |
| Middlesex, MA | 405,045 | 269,511 |
| Suffolk, MA | 929,612 | 618,550 |
| Hennepin, MN | 653,096 | 434,560 |
| Ramsey, MN | 918,292 | 611,018 |
| Jackson, MO | 239,000 | 210,401 |
| Essex, NJ | 138,747 | 92,320 |

## TARGETED ASSISTANCE ALLOCATIONS

### Counties for Targeted Assistance Program and Allocation - FY 1983-1984

| County, State | FY 1983 - Total Award | FY 1984 Proposed Allocation |
|---|---|---|
| Hudson, NJ | 928,433 | 617,765 |
| Union, NJ | 186,377 | 124,012 |
| New York, NY | 2,071,504 | 1,378,347 |
| Multnomah, OR | 1,407,416 | 936,473 |
| Philadelphia, PA | 963,382 | 641,020 |
| Providence, RI | 688,095 | 457,848 |
| Harris, TX | 1,129,253 | 751,388 |
| Salt Lake, UT | 343,292 | 228,421 |
| Arlington, VA | 594,897 | 395,835 |
| Fairfax, VA | 717,333 | 477,302 |
| King/Snohomish, WA | 1,713,650 | 1,140,237 |
| Pierce, WA | 366,222 | 243,679 |
| TOTAL | $ 58,883,586 | $ 39,999,998 |

## TARGETED ASSISTANCE ALLOCATIONS

The formula allocations, distributed by State, for FY 1983 and FY 1984 is:

### Targeted Assistance

| State | Total FY 1983 for Refugees and Entrants | Proposed FY 1984 for Refugees and Entrants |
|---|---|---|
| California | $ 23,576,618 | $ 16,352,947 |
| Colorado | 500,518 | 333,037 |
| District of Columbia | 54,738 | 36,422 |
| Florida | 15,897,951 | 10,578,255 |
| Hawaii | 551,152 | 366,728 |
| Illinois | 2,358,440 | 1,722,678 |
| Kansas | 616,952 | 359,640 |
| Louisiana | 420,836 | 280,438 |
| Maryland | 512,735 | 341,166 |
| Massachusetts | 1,334,657 | 888,061 |
| Minnesota | 1,571,388 | 1,045,578 |
| Missouri | 239,000 | 210,401 |
| New Jersey | 1,253,557 | 834,097 |
| New York | 2,071,504 | 1,378,347 |
| Oregon | 1,407,416 | 936,473 |

TARGETED ASSISTANCE ALLOCATIONS

| State | Total FY 1983 for Refugees and Entrants | Proposed FY 1984 for Refugees and Entrants |
|---|---|---|
| Pennsylvania | 963,382 | 641,020 |
| Rhode Island | 688,095 | 457,848 |
| Texas | 1,129,253 | 751,388 |
| Utah | 343,292 | 228,421 |
| Virginia | 1,312,230 | 873,137 |
| Washington | 2,079,872 | 1,383,916 |
| TOTAL | $ 58,883,586 | $ 39,999,998 |

## SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until Friday, March 30, at 9 a.m. when it will meet in this room to hear testimony from the Secretary of Health and Human Services, and from officials of the Offices of Human Development Services and Community Services.

[Whereupon, at 10:45 a.m., Wednesday, March 28, the subcommittee was recessed, to reconvene at 9 a.m., March 30.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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FRIDAY, MARCH 30, 1984

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, and Proxmire.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### OFFICE OF HUMAN DEVELOPMENT SERVICES

### STATEMENT OF DORCAS R. HARDY, ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES

### ACCOMPANIED BY DAVID A. RUST, DIRECTOR, OFFICE OF POLICY AND LEGISLATION, HUMAN DEVELOPMENT SERVICES

### PREPARED STATEMENT

Senator WEICKER. This morning we'll hear witnesses from the Office of Human Development Services followed by witnesses from the Office of Community Services. We have appearing before the committee today Dorcas Hardy, Assistant Secretary for Human Development Services, and then Dr. Harvey Vieth, Director of OCS.

If you would, follow the usual procedure of introducing your colleagues and then summarizing your prepared statements which will be included in the record in their entirety. Then we can get on to the questions.

[The statement follows:]

## STATEMENT OF DORCAS R. HARDY

I am pleased to appear before you today to discuss the fiscal year 1985 budget request for programs administered by the Office of Human Development Services.

A total of $5,368,301,000 is requested to support a variety of social programs which serve children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans. Of the total requested, $2,700,000,000 is requested for the Social Services Block Grant appropriation; $2,022,149,000 is requested for the Human Development Services appropriation; $4,250,000 is requested for the Human Resources Research and Demonstration appropriation; and $641,902,000 is requested for the Family Social Services appropriation. No funds are requested for the Work Incentive Program. The total requested for all programs administered by the Office of Human Development Services represents 95 percent of the comparable amounts available for these activities in fiscal year 1984. The reduction is consistent with the President's budget policy to limit Federal spending. Some of the reductions in formula grant programs reflect the Compact of Free Association with the Federated States of Micronesia and the Marshall Islands. Upon ratification of this compact, funds for these islands will be appropriated to the State Department.

With the exception of the Work Incentive Program, service levels for all programs supported in fiscal year 1984 will be maintained or increased to the extent possible through implementation of program and management initiatives. Support for discretionary activities which do not provide services has been substantially reduced.

Legislation will be proposed to reauthorize for three years the Head Start program, the Runaway and Homeless Youth program, Aging programs and programs which serve the developmentally disabled and Native Americans.

In Addition, a fiscal year 1984 supplemental in the amount of $43,200,000 is requested under the Family Social Services appropriation to meet prior year claims under the Foster Care program and to meet increasing numbers of claims under the Adoption Assistance program. As both of these program are open-ended entitlements, we are required by law to pay all allowable claims.

A level of $2,700,000,000 is requested for the Social Services Block Grant to continue support for a variety of social services through the States. The amount requested represents the full authorization for this program in fiscal year 1985. Services which a State may choose to provide may include, but are not limited to: child and adult day care services, protective services, foster care, transportation, training, information and referral, counseling, delivery of meals, and health support. Although no funds are requested for the Community Services Block Grant, States may use Social Services Block Grant funds to support those activities previously carried out under the Community Services Block Grant for which authority also exists under the Social Services Block Grant.

A level of $2,022,149,000 is requested for the Human Development Services appropriation. This appropriation includes programs for children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans.

For the Head Start program, $1,075,059,000 is requested to support the delivery of comprehensive child development services to 429,100 preschool children and their families, the same number served in 1984.

Funds in the amount of $80.4 million, which are estimated to be the value of the Head Start share of the United States Department of Agriculture's Child Care Food program, have been included in the Head Start request in an effort to simplify program management.

For the Administration on Aging, a level of $773,421,000 is requested. The request will provide a full range of supportive social services to 9.2 million older persons and nutrition services to approximately 3.2 million older persons. The requested appropriation includes funds for the Department of Agriculture administered food cash or commodities meals program for older persons. In order to simplify program administration at both Federal and State levels, the Administration proposes that States receive all elderly feeding funds from the Administration on Aging. In addition, legislation is proposed to consolidate all title III formula grant authorizations to provide maximum flexibility at the State level to meet local priorities and needs. The Administration will soon transmit to the appropriate authorizing committees a legislative proposal to make this change.

For Developmental Disabilities programs a level of $64,200,000 is requested. The program will continue to support State systems which coordinate, monitor, and evaluate services provided to the developmentally disabled; to provide for systems of protection and advocacy of individual rights of persons who are developmentally disabled; to provide support for University Affiliated Facilities; and to increase private sector employment for developmentally disabled people.

For Native American programs, $28,000,000 is requested to promote social and economic self-sufficiency for American Indians, Alaska Natives and Native Hawaiians.

An amount of $64,245,000 is requested for Human Development Services Program Direction. These funds will provide effective and efficient management of all programs administered by the Office of Human Development Services.

A level of $4,250,000 is requested for the Human Resources Research and Demonstration appropriation and will support research, demonstrations, training, evaluations, and dissemination of successful approaches in the areas of child welfare, day care, youth, child and family development, child abuse and neglect, and cross-cutting research, including technology transfer. These activities were supported at a level of $21,391,000 in 1984.

A level of $641,902,000 is requested for the Family Social Services appropriation. The Administration will propose legislative changes in the Foster Care program that will improve State incentives to effect early reunification or other permanent placement of children. Funds requested will continue to provide assistance to States to strengthen the family unit, to reunify children with their families, or, where this is not possible, to find suitable adoptive homes for them. These funds will support the Child Welfare Services and Training Program, and the Foster Care and Adoption Assistance Programs.

The Work Incentive Program is proposed for phase-out in 1985 because, as studies by the General Accounting Office have demonstrated, this program has not proven to be cost effective. Legislation will be proposed requiring work experience programs under the Aid to Families with Dependent Children program. States will be able to use unexpended carryover balances for phase-out activities in 1985.

Thank you, Mr. Chairman. My colleagues and I will be happy to answer any questions you and the committee may have.

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## BIOGRAPHY OF DORCAS R. HARDY

| | | |
|---|---|---|
| NAME | : | Dorcas R. Hardy |
| POSITION | : | Assistant Secretary, Office of Human Development Services |
| BIRTHPLACE AND DATE | : | Newark, New Jersey, July 18, 1946 |
| EDUCATION | : | B.A., Connecticut College, New London, Connecticut, 1968 |
| | : | M.B.A., Pepperdine University, Los Angeles, California, 1976 |
| | : | Executive Program in Health Policy and Financial Management, Harvard University, December, 1978 |
| EXPERIENCE | | |
| Present | : | Assistant Secretary, Office of Human Development Services |
| 1974-1981 | : | Associate Director, Center for Health Services Research, University of Southern California School of Medicine, Los Angeles, California |
| 1974 | : | Health Consultant, Urban Management Consultants, San Francisco, California |
| 1973-1974 | : | Assistant Secretary for Health, California Health and Welfare Agency, Sacramento, California |
| 1971-1973 | : | Executive Director of Health Services Industry Committee, Cost of Living Council, Washington, D.C. |
| 1970-1971 | : | Special Assistant to National Chairman and Director, White House Conference on Children and Youth, Washington, D.C. |
| 1970 | : | Legislative Research Assistant, Senator Clifford P. Case, Washington, D.C. |

### Office of Human Development Services
### Social Services Block Grant
(dollars in thousands)

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1985 Estimate |
|---|---|---|---|---|
| Social Services Block Grant | $2,675,000 | $2,440,000 | $2,675,000 | $2,700,000 |
| Human Development Services: | | | | |
| Administration for Children, Youth and Families | | | | |
| 1. Head Start | $988,350 | $1,050,650 | $995,750 | $1,075,059 |
| (Child Abuse Feeding) | (76,350) | (76,350) | (—) | (80,400) |
| 2. Child Abuse and Neglect | | | | |
| a. State Grants | 6,720 | 6,720 | 6,720 2/ | 6,720 |
| b. Discretionary Activities | — | — 2/ | 9,479 1/ | — 4/ |
| 3. Runaway Youth | 21,500 | 10,514 | 23,250 | 10,504 |
| Subtotal, Administration for Children, Youth and Families | 1,016,570 | 1,067,884 | 1,035,199 | 1,092,283 |
| Administration on Aging | | | | |
| 1. Grants for State and Community Programs on Aging | 759,641 | 709,896 | (646,141) | 760,746 |
| 2. State Agency Activities | (21,673) | (19,928) | 21,673 | (21,598) |
| 3. Supportive Services and Centers | (240,869) | (240,869) | 240,869 | (240,362) |

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1985 Estimate |
|---|---|---|---|---|
| 4. Nutrition | | | | |
| a. Congregate Meals | (319,074) | (290,949) | 321,574 | (320,892) |
| b. Home-delivered Meals | (62,025) | (58,150) | 62,025 | (61,894) |
| c. U.S.D.A. Commodity Program | (116,000) | (100,000) | --- | (116,000) |
| 5. Supportive Services for Employment and Economic Development (non-add) | --- | [277,100] | --- | --- |
| 6. Grants to Indian Tribes | 5,735 | 5,735 | 5,735 | 7,500 |
| 7. Research, Training and Discretionary Projects | 22,175 | 5,000 | 22,175 | 5,000 |
| 8. Federal Council on Aging | 175 | 175 | 175 | 175 |
| Subtotal, Administration on Aging | 787,726 | 720,806 | 674,226 | 773,421 |
| Administration for Developmental Disabilities | | | | |
| 1. Basic State Grants | 43,180 | 24,674 | 43,750 | 45,400 |
| 2. Protection and Advocacy | 7,320 | 7,303 | 8,400 | 8,400 |
| 3. Special Projects | 2,500 | 2,294 | 2,447 | 2,600 |
| 4. University Affiliated Facilities | 7,500 | 7,027 | 7,413 | 7,800 |
| Subtotal, Administration for Development Disabilities | 60,500 | 41,298 | 62,010 | 64,200 |

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1985 Estimate |
|---|---|---|---|---|
| Administration for Native Americans | | | | |
| 1. Financial Assistance Grants | 26,300 | 22,466 | 27,300 | 26,300 |
| 2. Training and Technical Assistance | 1,000 | --- | 1,000 | 1,000 |
| 3. Research, Demonstration, and Evaluation | 700 | --- | 700 | 700 |
| Subtotal, Administration for Native Americans | 28,000 | 22,466 | 29,000 | 28,000 |
| Salaries and Expenses | 65,053 | 63,892 | 65,412 | 64,245 |
| (Positions) | (1,340) | (1,184) | (1,340) 3/ | (1,262) |
| Total, Human Development Services | $1,957,849 | $1,916,346 | $1,865,847 | $2,022,149 |

1/ Funds for similar activities requested under the proposed Human Resources Research and Demonstration appropriation.

2/ Funds made available under the Second Continuing Resolution. P.L. 98-151.

3/ Actual allocated ceiling was 1,297.

4/ Funds to support similar activities are requested under the Human Resources Research and Demonstration appropriation.

### Office of Human Development Services
### Human Resources Research and Demonstration
(dollars in thousands)

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1984 Revised Estimate | 1985 Estimate |
|---|---|---|---|---|---|
| Social Services Discretionary Activities | 21,999 | $9,250 | --- | $21,391 | $4,250 |
| 1. Child Welfare Research and Demonstration | (10,608) | --- | --- | (10,000) | --- |
| 2. Child Abuse Discretionary Activities | (9,479) | --- | --- | (9,479) | --- |
| 3. Adoption Opportunities | (1,912) | --- | --- | (1,912) | --- |
| Total....... | $21,999 | $9,250 | $--- | $--- a/ | $4,250 |

a/ In 1984, funds for Child Welfare Research and Demonstration and Adoption Opportunities were appropriated under the Family Social Services appropriation. Funds for Child Abuse Discretionary activities were appropriated under the Human Development Services appropriation.

### Office of Human Development Services
### Family Social Services
(dollars in thousands)

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1984 Revised Estimate | 1985 Estimate |
|---|---|---|---|---|---|
| Child Welfare Services and Training | $160,149 | $156,326 | ($168,823) | $168,823 | $168,823 |
| 1. Child Welfare Services | (156,326) | (156,326) | 165,000 | (165,000) | — |
| 2. Child Welfare Training | (3,823) | — | 3,823 | (3,823) | — |
| Foster Care | 395,000 | 440,170 | 440,170 | 478,470 3/ | 460,279 |
| Adoption Assistance | 5,000 | 5,000 | 5,000 | 9,900 4/ | 12,800 |
| Child Welfare Research and Demonstration | — | — 1/ | 10,000 | — 5/ | — 2/ |
| Adoption Opportunities | — | — 1/ | 1,912 | — 5/ | — 2/ |
| Total, Family Social Services | $560,149 | $601,496 | $625,905 | $657,193 | $641,902 |

1/ Funds for similar activities requested under the proposed Human Resources Research and Demonstration appropriation.

2/ Similar activities may be carried out under the proposed Human Resources Research and Demonstration appropriation.

3/ A supplemental of $38,300,000 is requested to meet prior year claims.

4/ A supplemental of $4,900,000 is requested to meet current and prior year claims.

5/ Funds are shown under the Human Resources Research and Demonstration appropriation.

### Office of Human Development Services
### Work Incentive Program
(dollars in thousands)

| | 1983 Actual | 1984 President's Estimate | 1984 Appropriation | 1984 Revised Estimate | 1985 Estimate |
|---|---|---|---|---|---|
| Grants to States | $256,760 | — | $256,760 | 256,760 | — |
| Program Direction and Evaluation | 9,811 | — | 14,000 | 9,772 | — |
| Total, Work Incentive Program | $266,571 | $— | $270,760 | $266,532 a/ | — |

a/ The difference between the 1984 appropriation and the revised estimate reflects a comparable transfer to the Department of Labor.

### BUDGET REQUEST

Ms. **Hardy**. Thank you, Senator. I have with me David Rust who is Director of the Office of Policy and Legislation in Human Development Services. I have submitted testimony for the record and would just like to comment on some of that.

We are pleased to appear before you to discuss the fiscal year 1985 budget request which is for a total of $5,368,301,000. That is requested to support a variety of social programs for children, youth and families; for the elderly; for the developmentally disabled; and for native Americans.

We have a common goal in Human Development Services in all our programs of trying to develop and maintain social and economic self-sufficiency. Our budget reflects our policy that the well-being of the public is primarily a responsibility of individuals, of families, and of the communities in which they live; and that needed services are best defined and administered at those levels.

However, when services are needed for our vulnerable populations, we look to the Federal Government, State and local governments, and the private sector to address the issues.

We have, in this budget request, reduced some of our levels of support for discretionary research, for administration, and for evaluation activities which don't provide direct services. We expect to maintain or increase our levels of direct services without additional funding. This would be accomplished through implementation of program and management initiatives.

An example is the Head Start Program where services would continue to be provided to at least the 430,000 children and their families currently being served.

Another example is the aging programs where both the levels of service and the number of meals are expected to increase over our 1984 levels. We anticipate we'll serve about 218 to 220 million meals to the elderly in 1985, an increase of approximately 6 million meals over 1984.

We also plan to continue a national adoption initiative that was begun in 1983. This initiative focuses on reducing the number of children who are in foster care in this country and successfully placing the 50,000 children who are legally available for adoption.

I anticipate that we will continue to be successful and will be able to federally subsidize an increasing number of children this year and probably more next year.

We also plan to continue our initiative focusing on employment and placement of developmentally disabled individuals in competitive employment. We have set a target of placing 25,000 individuals during 1984.

We anticipate that that will contribute to social and economic self-sufficiency for our developmentally disabled individuals. We are working very closely with our reservation and urban Indian communities to promote social and economic self-sufficiency.

We believe that we have considered the alternatives and have constructed a budget that applies our resources very efficiently and very effectively; and, at the same time, still provides the services that our vulnerable populations need.

Mr. Rust and I would be glad to answer any questions you and your committee may have. Thank you.

### INCREASE FOR SOCIAL SERVICES BLOCK GRANT

Senator WEICKER. Your statement correctly points out that no funds are requested for the community services block grant for which $346 million was provided in 1984. In your statement you say "The Department proposes that States use other sources of funding, including the social services block grant."

How much of an increase are you requesting for the social services block grant to compensate for the loss of funds to the community services block grant?

Ms. HARDY. We have requested an appropriation of $2.7 billion in fiscal year 1985, which is the full level authorization for the social services block grant.

Senator WEICKER. And what is that?

Ms. HARDY. The increase is $25 million.

Senator WEICKER. So you're, in effect, cutting $346 million and replacing it with $25 million. How else is this going to be accomplished?

Ms. HARDY. We have proposed this change in the past, and believe that there are many services that are duplicated between the two programs. Many of those CSBG services can be provided by the social service block grant.

I should also add that Dr. Harvey Vieth, as you noted, is here as head of the Office of Community Services and Jerrold Speers, the Deputy Director of the Office of Community Services. Perhaps they have some other comments to add on that.

Senator WEICKER. Well, I haven't received their statement. Let's limit this to ask you some questions here.

Ms. HARDY. Certainly.

### IMPACT OF PROPOSALS ON LOW-INCOME FAMILIES

Senator WEICKER. You're proposing that the social services block grant, the major Federal program funding child care systems, be absorbed in the community services block grant with an overall cut of $320 million. You're also, once again, proposing the idea or objective from last year of having Head Start directly commence child care feeding activities now provided by the Agriculture Department. This raises concerns that future appropriations might not adequately meet nutritional needs covered by the Child Care and Feeding Program.

You further propose elimination of a $166 million work incentive program that provides child care for welfare recipients enrolled in job training projects.

It seems to me—and I'd like your comments—that these proposals make it even more difficult for low-income families to become self-sufficient or keep their jobs.

Ms. HARDY. We believe that there's a duplication in what the community services block grant and the social services block grant are funded to do at the community level; that we can provide many of those same services with elimination of the community services block grant as it currently stands.

In the Head Start request we have proposed to transfer to Head Start child care feeding funds currently appropriated to the Department of Agriculture. We anticipate that that would be a better administrative mechanism for the Head Start grantees.

We have proposed the elimination of the WIN Program. We have seen over the years that the WIN Program is not as successful as we would like it to be; that there are other programs through the Job Training Partnership Act and through the work-fare proposals that we believe can produce the same kinds of employment opportunity for low-income individuals.

### DETERIORATION OF SERVICES IN CONNECTICUT

Senator WEICKER. I would like to call your attention to a booklet recently published by the Connecticut Association for Human Services and the Junior League of Hartford entitled "Growing up at Risk in Connecticut". Just a few excerpts from the publication will clearly illustrate the deterioration of services in recent years to children desperately in need of help.

I'm now quoting from the work.

> One in seven children under six lives below the poverty level. Between 1970 and 1980, the poverty rate for children under six in Connecticut increased by 58 percent.
>
> In 1973, Connecticut's AFDC grant was set at 91 percent of the poverty level. Currently it is set at only 66 percent of the poverty level for a family of three.
>
> Between 1980 and 1983 in Federal funding alone there has been a 22.3-percent decrease for children's programs in Connecticut. The vast majority of publicly funded day care centers which are open to low income families have waiting lists.
>
> Only one-quarter of eligible children are enrolled in Head Start programs. There are soup kitchens and emergency food banks in Connecticut reporting increased demand for assistance of up to 400 percent since 1980. There is a notable increase in the number of families with children requesting help.

Now, there is the way your programs have impacted in the State of Connecticut. I'd like to hear your comments on that track record.

Ms. HARDY. I would like to see the report and be able to respond more fully. I think there are some things that perhaps have happened in the State of Connecticut that we cannot say are totally based on any kind of decreases from a Federal standpoint.

When you look at the social services block grant, which as you said earlier is the largest of the block grants that are going to the State, the 22-, 29-, 30-percent decreases being quoted are not accurate. There are large sums of dollars there. We think they're being used efficiently.

I don't have all the details of the State of Connecticut in terms of the absolute numbers. I think we've been providing level funding in many of our cases for children's programs. I see that in most of the States day care is still an important program. Many of the States continue to fund day care at the same level that they did before.

Mr. RUST. Could any of that be recession-related also, Senator, rather than a budget consequence?

Senator WEICKER. No; because, quite frankly, Connecticut came through the recession, I think, relatively well. They never achieved the unemployment levels that other States did. It is a State whose per capita income is one of the highest in the Nation.

Yet this kind of report is coming out of the State of Connecticut. I wouldn't like to see what it's like in some of the other States.

But I hardly think that the Connecticut Association for Human Services and the Junior League of Hartford are some wildeyed Communist liberal group that's trying to undermine the administration. I think this is just plain cold, hard fact as to what is said.

We'll be glad to go ahead and supply you a copy of it and I would very much appreciate comments on it. If you feel in anyway that it misrepresents the case, please let us know.

### HISTORICAL FUNDING FOR SOCIAL SERVICES BLOCK

Counsel tells me the social service block grant was $3 billion in fiscal year 1981, $2.7 billion requested for fiscal year 1985. So over a 4-year span you've actually gone down, never mind the inflation factors that have been present during that time, in straight dollars. When you apply the inflation it is what for fiscal year 1985?

Mr. RUST. It's 4.6 percent, Senator.

Senator WEICKER. I wonder how much further down it really is. How do you explain it? How do your people take care of it?

Ms. HARDY. What we have said is that we believe that there's far more significant impact, in the long term, when we have a healthy economy. That obviously has been the adminisration's primary target over its first couple of years and we think we're doing a pretty good job in that area.

That's why I was asking about some of these figures. I think there's a correlating decrease in poverty when we have better economic growth in terms of the whole country.

### IMPACT OF PROPOSED REDUCTIONS

Senator WEICKER. I would make a suggestion, that you leave the economics, which are bad enough, at the present time to Martin Feldstein and others. You have some specific responsibilities to some specific people here.

Indeed, if anybody got caught up in the grinder, they did as far as straightening out the economic mess. Let's accord you and the administration the credit for a job well done.

The fact remains that a lot of people were very, very hurt, and still are. I have no doubt that the upper-income groups in those States are doing very well.

To put it in other terms, I am chairman of the Small Business Committee; the large corporations in America have had a tough time during the past couple of years but they managed to make it through. In the last couple of years, we've averaged out 12,000 to 13,000 small businesses going under; they couldn't survive.

Now, what we're talking about is people here. We're talking about those that need the special care of society and at a time like this more than ever. That's why I don't understand these cuts in these programs. I really don't.

I don't follow it. I don't see how you're doing more for the ones that you're supposed to help.

### CHILD CARE FEEDING PROPOSAL

Your budget justification states "In 1985, Head Start programs will no longer receive Department of Agriculture reimbursements. Instead they'll receive these funds directly as part of their Head Start grants."

Does this mean you plan to proceed administratively to implement a change that was rejected by Congress last year?

Ms. HARDY. No; we are proposing that. That is part of our budget request that would require legislation. That is part of our Head Start reauthorization request and it's also in Agriculture.

Mr. RUST. That requires a change in the USDA authorizing legislation. They're submitting that.

### MAINTENANCE OF HEAD START ENROLLEES

Senator WEICKER. How do you expect to maintain last year's level of Head Start enrollees when you're not requesting increased funding to offset inflation?

Ms. HARDY. We have been working through the Head Start cost management and cost improvements with the grantees to insure that they are very well run and that they have no carryover balances. We believe these improvements will offset inflation.

Senator WEICKER. Senator Proxmire?

### REITERATION OF PROBLEMS IN CONNECTICUT

Senator PROXMIRE. Thank you, Mr. Chairman.

Secretary Hardy, I think that the point that the chairman has made is one that deserves to be underlined. It's a very good point.

Connecticut probably is the richest State in the lower 48. Only Alaska is richer, and only because they have a much higher cost of living and other unique conditions.

At any rate, the plight of children in Connecticut is appalling under these circumstances. You would think that this very rich State, compared to others, would be in much better condition. I think it does underline the importance of doing more than we're doing.

### DISCUSSION WITH DR. VIETH

I have some questions for you. Before I get to that, though, I'd like to ask Mr. Vieth a question. Mr. Vieth, looking at your résumé I was astonished to see that you graduated from Ripon High School, Ripon, WA. Is that a mistake?

Mr. VIETH. That is a mistake.

Senator PROXMIRE. Thank heavens.

Mr. VIETH. It's Wisconsin and I'm proud of it.

Senator PROXMIRE. Well, that's great to hear. [Laughter.]

You see, this also explains why you're a Republican. Ripon is the birthplace of the Republican Party.

Mr. VIETH. I understand that very well.

Senator ANDREWS. Well, I'm sure a number of good things happened in Wisconsin. [Laughter.]

Senator PROXMIRE. You went on from Ripon to Marquette University and then you fell away, unfortunately. [Laughter.]

Mr. VIETH. I go back on occasion.

Senator PROXMIRE. Well, that's great. If you have to be a Republican, I suppose being a Ripon Republican gives you a reason to be forgiven.

Senator ANDREWS. You better watch out. You might be painting Dr. Vieth, here, with a brush that I'm not so sure he would appreciate. [Laughter.]

You said the Republican Party was founded in Ripon; not this Republican Party. [Laughter.]

Senator PROXMIRE. Well, when you look at the rest of Mr. Veith's résumé—chairman of Reagan for President, El Paso County, et cetera, et cetera—it's pretty impressive.

### COMPLIANCE WITH REPORT LANGUAGE

Now, Secretary Hardy, yesterday I received a letter from Secretary Heckler regarding departmental compliance with language contained in last year's report. As you'll recall, the report mandated a funding level for national legal services organizations. Secretary Heckler responded that funding for these organizations, and I quote, "* * * will depend on the outcome of a competitive grant review process."

### GRANT REVIEW PROCESS

Some serious questions have been raised in the press and by your Inspector General about the extent to which your grant review process is truly competitive. Last October a story appeared in the Washington Post which said the following:

> Officials in a Health and Human Services Department program to give millions of dollars in grants to social science projects have been approving projects rated by experts as the lowest of their class and rejecting others that are highly ranked. * * * Staff members of the Department's Office of Human Development Services and researchers who receive grants from it say the OHDS Research Grant Program has been transformed.
>
> One researcher called the grant decisions "totally unpredictable" and one staff member said, the grant system now is "pure pork barrel."

Let me quote an example from the Washington Post story. "In a program aimed at aiding homeless children and runaways, 5 of the top 12 proposals were rejected despite scores of 86.5 to 91. At the same time, proposals ranked 100, 101, and 103 were approved for consideration for grants. They scored between 56 and 58.5."

How do you respond to those charges?

Ms. HARDY. Well, the first comment I would like to make about that, Senator, is that the Inspector General's report that you referred to does not correlate to any other piece of the discretionary activity that you're talking about. The Inspector General's report is based on practices which occurred before I came to office.

In terms of the Coordinated Discretionary Program that we have tried to put together—and I would welcome having a further opportunity to give you a briefing about how all of it works and what we are trying to do—basically our figures indicate that 44 percent of the projects that were funded were ranked in the top 10 percentile and 64 percent of them were ranked in the top 20 percentile.

So in terms of the numbers that we're looking at we think we're doing a very good job.

Taking into account the reviewer's comments is a part of the process. That is not the only thing that is taken into account when we go through the Coordinated Discretionary Program.

In the case of those runaway program proposals that you're referring to, we can supply you with specific reasons and information, but I would tend to think it was because they were shelters and bricks and mortar and specific programs that the reviewers were obviously not aware that we had similar projects in other areas of the country or other areas nearby to where those people applied.

We obviously take into account exactly the criteria that we put in the Federal Register. We feel that it's a very good process and it has opened up the entire social services field, made it easier to apply with shorter applications, made it so that we are not the sole supporter of beltway bandits and consulting firms; that we are trying to involve locally based and community based organizations in innovative ways with social services moneys.

## SELECTION OF FUNDED APPLICATIONS

Senator PROXMIRE. Now, the Post story quotes you as saying that an application ranked in the highest 25th percentile of the reviewers' scores had a 600-percent higher probability of being selected than one ranked in the lowest 25th percentile. In other words, the high scoring grant was six times more likely to be funded.

By way of contrast, the Director of the National Science Foundation Program, which makes similar grants, said, and I quote: "It would be impossible, I think, for a grant to be ranked poor, in the bottom 20 percent, and still be funded. It would also be very rare that a proposal ranked excellent, in the top 20 percent, does not get funded."

Now, you obviously don't agree with the NSF approach, but why should you ever fund a program in the bottom fourth of the rankings?

Ms. HARDY. Because it's innovative in that area; because it's deemed by us to be important to that community; that it was something very unusual for that community. We can give you a list of the ones that were funded that were, as you said, at the lower percentile. They were perhaps not particularly well written but good ideas and locally based.

Senator PROXMIRE. Well, I hope you'll give us that list because, as I say, the National Science Foundation has quite a different view and it seems to me to be more logical. The Foundation simply wouldn't fund a program that has a very low rating when it wasn't funding some of the highest rated programs.

Ms. HARDY. Senator, often the lower scored ones were projects serving minorities. For example, we have funded one in Illinois: That's family oriented family focus, in Evanston, Illinois, that I happen to be familiar with. They are working with Hispanic parents at the worksite.

That's something that's very unusual. It's trying to keep families together; it does not cost much money, and I believe it is being matched by the State. We felt that it would be worthwhile in terms of our goals to provide services to needy minorities.

I also should comment that I felt, when that article came out, that it was misleading to have social sciences compared to the National Science Foundation. We are not a clinical/scientific/study/research kind of operation.

The social science/social services area, just by its very nature, is not nearly as technical, as scientific, as the National Science Foundation.

Senator PROXMIRE. For the record, will you provide a list of those ranked in the lower 20 percent that you did fund?

Ms. HARDY. We certainly can.

[The information follows:]

## FUNDED GRANTS

Out of 225 grants awarded, 7 applicants were awarded grants under the fiscal year 1983 Coordinated Discretionary Program with scores on their preapplications below the 20th percentile. These seven grants are:

International City Management Association, "Reducing Hispanic Youth Unemployment: A Demonstration Effort Using Public/Private Partnerships".

The Menninger Foundation, "Project Independence: A Partnership Program to Improve Private Sector Employment of Persons with Developmental Disabilities".

St. Francis College, "Facilitating Learning to Operate Microcomputers for Older, Unemployed, and Job Retraining Learners".

Indianapolis Urban League, "Career Counseling and Employment Program for Single Heads of Household and Their Children".

United Indians of All Tribes, "An Innovative Employment Project for Native Americans Residing in Seattle/King County".

Family Focus, "Prevention Strategies for Social and Economic Self-Sufficiency in High Risk Adolescents".

National Coalition of Hispanic Mental Health and Human Services Organizations [COSSMHO], "Primary Prevention on Strategies with Low Income Hispanic Families".

## RESEARCH AWARD PROCESS

Senator Proxmire. My last question on the research award process has to do with a comment made to the Post reporter by one of your staffers who, for obvious reasons, wishes to remain anonymous. He said that at times writing a letter of approval becomes a joke.

As an example he cited an instance of someone handing him an application that scored below 50 but was approved for funding and telling him to "see if you can find me something good to say about that one, anything at all." How would you explain to that worker why you had chosen the lower ranking project?

Ms. Hardy. I would need to see the copy of the application or see the notes that are kept on decisions. I was unaware until it was printed that it was something that had been said by a staffer.

I believe that's inappropriate. I believe we have solid reasons for every one that we have funded; and we can certainly supply those.

This is the third year of this Coordinated Discretionary Program. It's, I think, even smoother and better, and does provide the broad opportunity for the local communities to get involved even more so as we go through the process.

We had approximately 5,000 applications the first year. We had about 3,000 or so this year. So that's considerably less than when we first started.

We've been more specific in the Federal Register so that people have clearer, tighter proposals coming in; and we think we have a very good process.

## FREQUENCY OF SITE VISITS

Senator Proxmire. An Inspector General's report submitted to you on September 23 of last year pointed out that in 35 of the 49 active grants they examined there was no evidence of site visits.

The report cited an example of a grantee located right here in the District of Columbia who was never visited during a 15-month period although he lost the principal investigator, he had to request a 3-month extension and employed a consultant to complete the grant objectives. Another District of Columbia grantee was visited once over a 27-month period and the final report was termed useless by program officials.

On the other hand, the IG's report indicated that a grant recipient located in Egypt was visited eight times by various program officials at a cost of $20,000.

Your response to these comments refers to a lack of staff resources and travel funds. If that's the case, how were you able to find the funds for eight visits to Egypt——

Ms. Hardy. I didn't fund them.

Senator Proxmire [continuing]. When you couldn't monitor two grantees in the District of Columbia?

Ms. Hardy. I would like to submit my comments back to the IG for the record here because most of those events occurred before I came into office. The IG report was very late. I do not feel that I should be personally held responsible for them.

In the current grants that we have underway, my staff has promoted the concept that we need to have site visits, that we need to have better trained project officers, and that we obviously are not in the business of funding large international travel budgets.

Those kinds of things have not been occurring in the last 3 years.

Senator PROXMIRE. Well, the Inspector General's report of last year indicates that in 35 of the 49 grants examined there was no evidence of site visits. You say these problems did not occur in the last 3 years?

Ms. HARDY. That's correct. The report that I sent back to the IG indicates most of those occurred before I came into office.

I'm concerned that we run a good process. Obviously, I am appreciative of your comments because we are trying to run a good process. I believe we can document that. This is true whether the grants are part of the Coordinated Discretionary Program, which is certainly not all of our grants, or if they're outside of that coordinated process and within each of the programs.

I believe that the money is well spent. Getting our money's worth is very important.

Senator PROXMIRE. Well, for the record, would you indicate when these inspections did or didn't take place——

Ms. HARDY. Yes.

Senator PROXMIRE [continuing]. Both in the District of Columbia and in Egypt?

Ms. HARDY. Yes; certainly.

[The information follows:]

### INSPECTIONS OR SITE VISITS

During the past 4 years, staff of the Office of Human Development Services have made five site visits to grantees in Egypt. Each site visit was in conjunction with travel to grantees in other countries. Expenditures for each visit are paid for mainly by the Egyptian Government since these projects are funded under Public Law 480. The dates of the Egyptian site visits and the amount of Office of Human Development Services funds expended for each site visit are:

| | |
|---|---|
| March 2-11, 1981 | $385 |
| February 7-15, 1982 | 200 |
| March 3-10, 1982 | 220 |
| February 12-20, 1983 | 150 |
| April 10-19, 1984 | 300 |
| Total | 1,255 |

We do not have records, however, of the dates for the site visits made in the District of Columbia since travel funds are not involved.

### COMMUNITY ACTION AGENCIES RUNNING HEAD START PROGRAMS

Senator PROXMIRE. I understand that a number of agencies receiving community service block grant funds also run Head Start programs. Can you give us some idea as to how many Head Start programs are run by the community action agencies?

Mr. RUST. Head Start has approximately 1,200 programs. Out of that 1,200, 800 are and 400 are not run by community action agencies.

### ADMINISTRATIVE COSTS

Senator PROXMIRE. Is it logical to expect that the administrative costs paid for with Head Start funds, Dr. Vieth, should be lower when a program is run by a community action agency which also receives funds from a CSBG program?

Mr. VIETH. We cannot substantiate that. In the few that we've looked at across the board there's a mix. So, in fact, the fact that community action agency is housing the Head Start Program does not show that the administrative costs are less.

Senator PROXMIRE. As a practical matter, how do the administrative costs of the Head Start programs run by community action agencies compare with the administrative costs of nonaffiliated Head Start programs?

Ms. HARDY. About the same.

Mr. VIETH. They're about the same.

Senator PROXMIRE. They are about the same?

Mr. VIETH. Yes.

### SUPPORT FOR PREVENTION OF FAMILY VIOLENCE

Senator PROXMIRE. I have one more question. Secretary Hardy, you're requesting $642 million for family social services next year and also fund programs to combat child abuse and assist runaway youth.

I recently read that the State of Massachusetts Department of Health has contracted for the development of a curriculum for use in schools and community settings which would decrease the prevalence of family violence through increasing the abilities of individuals to identify and cope with stress by constructive and nonviolent means.

Has your office supported any work in this area or does it have any plans to pursue that kind of an approach?

Ms. HARDY. I don't think we supported that specific curriculum, but we have supported family-oriented curricula and training throughout the country through our preventive child abuse programs and through our positive family focus programs.

Senator PROXMIRE. Thank you. Thank you, Mr. Chairman.

Senator WEICKER. Senator Andrews?

### MISSING CHILDREN

Senator ANDREWS. Mr. Chairman, you've asked many of the questions, along with Senator Proxmire, I had but I have a couple that still concern me.

Three or four weeks ago a major news magazine, in its cover story, talked about the tragedy of the missing children. As I recall—and I'm a member of the Senate Children's Caucus—this is one of the key things that we're concerned about.

Senator Hawkins, I think, was quoted in there. The President was quoted in there saying he's going to really do something about this. This is a major objective of this administration.

Yet when I look at your budget request, again the administration gives lip service to it, national news magazine article cover story and all of the rest. Last year we appropriated $23 million for runaway youth. In fiscal 1985 you're proposing $10.5 million.

Every year the administration has proposed about $10 million. Each year the Congress, because we're aware of the problems, has at least doubled that request.

Now, in this article, we get all of the rhetoric out of the White House, but we still get the funding that can help to accomplish the resolution of some of this problem cut in half.

Why do you continue to ignore the action of the Congress in requesting funds for this program? And how can an administration, on the one hand, give lip service to a problem that's as acutely devastating as this one is and then, where it actually counts, where you get away from the promises and into the performance, back away from it?

Ms. HARDY. There are two things I would like to respond to. One is, on the Runaway Youth Program we have proposed a decrease because we think we can return to the historical level of funding.

The two years that the Congress has given us more money have been 1983 and 1984. Up until that time the program followed a 10-year pattern of approximately $10 million.

Senator ANDREWS. Isn't the problem worse now than it was?

### CORRELATION BETWEEN RUNAWAY AND MISSING YOUTH

Ms. HARDY. I don't see a direct correlation between the runaway youth shelters and missing children. The runaway youth shelters are dealing primarily with children in this country who run.

Most children run for about 3 days. About 70 percent of them run in the community in which they live. And those are not the missing children and those are not the murdered children and those are not the Adam Walshes.

We are working very closely with the Office of Juvenile Justice and Delinquency Prevention on the missing children situation. We will support May 25, missing children's day, and the whole awareness that obviously the film "Adam" and John Walsh and his family created through that movie.

I happen to have just been with Mr. Walsh this week and am working with him to make this a concern throughout the country. We anticipate that we will be working also with support groups of parents on the social services side to assist them if they have missing children. We are working with the media in terms of promoting the pictures and visibility of the particular missing children.

We're talking there about psychopathic murderers. We're talking there about pedophiles. We're talking about a different, a bigger, a worse problem.

On the runaway youth side we see that our shelters are serving individuals throughout the country. We see that approximately 25 percent of their money comes from the Federal Government. We are seeing a lot of them community supported, in receipt of a lot of local funds.

The new runaway shelters that were funded last year have applied for only 1-year grants knowing that they would be funded for only 1 year. One criteria for selection was the demonstrated ability of the grantee to continue to provide services after Federal funding terminated.

Senator ANDREWS. Right; but, Madam Secretary, the information that we get from experts in the field is about 180 degrees out of synch with that.

Certainly a part of the missing children are the ones who are forceably kidnapped or picked up by some sex deviate, or something like that; but a large number, they tell us, would not become missing children if there was, in fact and in place, these kinds of shelter, this kind of infrastructure to encourage them to report in that first 2 or 3 days of their leaving home.

They tell us that the way that you keep a child out of the missing children category is to get that child encouraged to return to home, to touch base with that child during the first 2 to 3 days, which is when your runaway shelter function is, in fact, working.

Now, how do you explain the total difference between that approach and the approach that you've just outlined to me?

Ms. HARDY. I was unaware of that.

Senator ANDREWS. In other words, they're saying that one of the best ways of cutting down these tragic statistics on missing children is to strengthen the Runaway Youth Program to, in effect, touch them in the first 2 to 3 three days.

Ms. HARDY. If we are talking about children who run away, I would agree, but I believe that children categorized as missing are not those who run away.

Senator ANDREWS. Well, you can understand the logic of that approach, I would hope.

Ms. HARDY. I'm not convinced that we're talking about the same population.

## IMPACT OF PROPOSED REDUCTION FOR RUNAWAY SHELTERS

Senator ANDREWS. As I understand the information I've been given, many of these children are tragically confused. They're temporarily at odds with their parents or whatever guidance group they're living with. And they leave.

If you can get them before they become preyed upon by individuals or groups who will do them harm, you've accomplished a great deal. But we see this pattern of administration again cutting in half the appropriations put out by Congress for this flying in the face of the statement the administration makes in the article of missing children, flying in the face of the entire Congress.

You think that you can explain it by saying that the shelters, themselves, have been applying for less and for termination at the end of a year? Isn't that brought about by virtue of the fact that you have undoubtedly had your people telling them, "Don't expect anything beyond a year; don't expect too much because we're cutting this program back"?

Ms. HARDY. For the new shelters, funded initially in 1983 and 1984, one of the criteria for selection that was published in the Federal Register was the ability of the grantee to continue after Federal support is withdrawn.

Senator ANDREWS. So, I mean, when you come in and say, "Well, they're not applying for more," maybe——

Ms. HARDY. No; I didn't say that. I said that that was how it was structured based on the fact that we had had 1-year funding from the Congress. We have said that those were the new shelters and we have also said that they all need to compete and make sure that they are well run and they're doing their job which they are paid to do.

Senator ANDREWS. Well, it's still a mystery to me how the two can justify in a comparison; but I'd appreciate it if you have any further thoughts on it if you could send them for the record so those of us on the subcommittee could have the benefit of them.

Ms. HARDY. Certainly.

### CROSSLINK BETWEEN RUNAWAY AND MISSING YOUTH

Mr. RUST. Senator Andrews, we have had a number of briefings by experts in the FBI on the runaways and whether there is that crosslink which you refer to. In the meetings I have sat in on, I've never heard that argument articulated before.

Do you have a particular expert or testimony that you're referring to?

Senator ANDREWS. Well, we can find that.

Mr. RUST. That would be helpful to us.

Senator ANDREWS. Otherwise, if you don't think that to encourage the child to come back in the first 2 or 3 days of absence would help cut into the missing children's statistics, then obviously we don't need this augmented Runaway Youth Program.

How else do you plan to handle the tragedy? The statistics that we have have to be the same as yours. Missing children is worse now than it was 3 years ago.

Mr. RUST. I'm talking about the kids that are actually kidnapped from their paper route, from their school bus. That's who we're talking about, not the ones whose father——

Ms. HARDY. Not a custody dispute.

Mr. RUST. Not custody where you're talking about the——

Senator ANDREWS. That's true, but——

Mr. RUST [continuing]. Two thousand to eight thousand kids a year who are snatched by pathological sex deviates and so forth. We have generally looked at that in our meetings with the Justice Department, the FBI. That's a very serious law enforcement problem.

Senator ANDREWS. Well, we're told generally that the young girls who go into prostitution don't intend to go into prostitution when they leave home originally. They drift away from home and because they aren't returned home in that first few days they're then out there to be preyed upon. They're separated from their home.

You know, the statistics are all around us on this and we're told that one of the ways of helping that from happening is to make sure that before they're out there for so long that they're baseless and ready to be preyed upon, you get them back by the use of some type of runaway youth program, some shelter program, some—you know how the underground works. A child gets discouraged at home and leaves for the nearby city or another city and if the word is out, the grapevine is out that you, in fact, have a runaway youth shelter maybe some of them will come.

But if you keep cutting down on the availability of these shelters, that word can't get out. That opportunity to return to a halfway house is not there; and that child turns from a temporary runaway to a missing child forced into prostitution, forced into drugs, forced into everything else.

Now, you know, I don't know why we have to draw statistics and who said what. How else do you get them back? Isn't this one of the better ways?

As I say, if you have some alternative to that theory I'd appreciate hearing it. I know the subcommittee would appreciate hearing it. You must have some alternative because you're cutting the funds by more than half at the same time the administration is saying they're concerned about missing children.

Senator WEICKER. If you would yield for 1 minute.

Senator ANDREWS. Sure, Mr. Chairman.

### JUVENILE JUSTICE

Senator WEICKER. You say that you're working on part of this problem over at the juvenile justice area?

Ms. HARDY. Yes; there will be a National Center for Missing Children established in May.

Senator WEICKER. Well, the administration request as I understand it for juvenile justice is zero.

Ms. HARDY. We are still going ahead with the establishment of the National Center for Missing Children, which will be started in May and I anticipate will continue to be partially funded.

Mr. RUST. In the Office of Justice Assistance, I think, rather than the Office of Juvenile Justice.

It will be within the Justice Department, but not in juvenile justice.

Senator ANDREWS. But you've touched on it, Mr. Chairman. There are these alternatives they talk about, but they don't put their money where their mouth is in any of these alternatives. That's the tragedy.

The problem continues. We give lip service but we don't deliver. One of the programs that has the capability of helping bring them back before they become another statistic, are forced into something that's extremely difficult to get them out of, is being cut in half.

As I say, if you could expand on that, we'd appreciate it.

## CHILD WELFARE PROGRAMS

For fiscal 1985 you requested $168 million for child welfare services and training. You haven't included separate funding for child welfare research and demonstration.

Will research and demonstration funding be included in services and training funds?

Ms. HARDY. No; it's not in the $168 million that you're talking about. It's in a proposed discretionary account.

Senator ANDREWS. So you don't have any separate delineated line item for child welfare research and demonstration.

Ms. HARDY. No; we do not. We are proposing that the child welfare research and development and the adoption opportunities and some of our other 1110 moneys be combined into one account for family social services research.

Senator ANDREWS. But there's really no, shall we say, priority applied to these programs. They're lumped off in that other category.

Ms. HARDY. They would be combined together and we would work with the Administration for Children, Youth, and Families in determining priorities and also work with the constituents and the research community on priorities.

## CONSOLIDATED DISCRETIONARY PROGRAMS

Senator ANDREWS. Is this expanded catchall category receiving as much in the way of funding as it did before?

Ms. HARDY. No; we are proposing less money.

Senator ANDREWS. So you're putting a group of programs into the catchall and saying, "Here we come, but the overall amount is less."

Ms. HARDY. Correct, given my proposals to focus dollars on direct services throughout HDS.

## NEED FOR CHILD WELFARE RESEARCH

Senator ANDREWS. Do you feel the need for child welfare research and demonstration is less now than it has been? Have we solved the problem? Do we know the answers?

Ms. HARDY. I think we can probably continue going on and spending the same amount of money and funding very similar projects forever and ever.

Senator ANDREWS. I don't think anyone wants to fund very similar projects. I think people want to find the answers and that's why I asked you: Do you think we've found the answers that we have the ability to find in this field? Is that why you've deemphasized that?

Ms. HARDY. Well, I'm not sure that research always finds the answers to why families split up or what causes the need for child welfare services. We think that we are proposing sufficient support to continue to do projects and demonstrations around the country that would be helpful.

Senator ANDREWS. But we're told, Senator Weicker and I, that the only way you develop the new military weaponry is through research to find the good ones that are cost effective. Sometimes I wonder, but we're told in Agriculture that the way you find the new herbicides and pesticides and better ways of treating the environment is through research.

The President's saying that the acid rain problem should be solved not by scrubbers and the rest, but by research to find out what goes on. In the key area of child welfare we say we don't need research; that we have all the answers, that we know how to handle it? In essence, that's what you're saying.

Ms. HARDY. We're saying that we could do with less research. I'm saying that if I had my choice in terms of where dollars should be put in this program that they should go into services just like we've done across the board in Human Development Services.

Senator ANDREWS. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Andrews.

The reduction in that area that you were discussing, Senator Andrews, is they are requesting an 80-percent reduction in funding from the current level of $21.4 million down to $4.2 million.

Senator ANDREWS. It's rather significant, Mr. Chairman.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have other questions to submit to you for response to the record, and for other Senators on the committee.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### DEVELOPMENTAL DISABILITIES UNOBLIGATED FUNDS

Question: In July, 1983, the Inspector General of HHS issued a report indicating that over $11 million appropriated for Developmental Disabilities State grants over a period of 9 years was unobligated. The report made several recommendations to the Administration on Developmental Disabilities to address this problem, including the issuance of policies for financial accountability.

Has the Administration on Developmental Disabilities issued such policies?

Answer: The Administration on Developmental Disabilities is working toward improving both the programmatic and financial management aspects of the Developmental Disabilities Program.

In fiscal year 1983, a policy work group collected all prior policies, reviewed them for current applicability, identified priority areas, and began updating and revising, as appropriate.

On February 23, 1984, the Secretary signed regulations for the Developmental Disabilities Program. These regulations were published in the Federal Register on March 27, 1984.

The Administration on Developmental Disabilities is working on a Policy Manual which will include programmatic and fiscal requirements in support of these regulations.

As policy is finalized, there is a system of on-going issuances such as program instructions, and information memoranda going to State grantees.

Development of policies for both the programmatic and financial management aspects of the Developmental Disabilities Program are a high priority in fiscal year 1984. We will continue our efforts to provide policy guidance to our grantees.

Question: What steps have been taken to insure that appropriated funds are expended?

Answer: The Administration on Developmental Disabilities, in concert with the Division of Grants and Contracts, through Regional Offices, monitors differences in unobligated balances between "nonfinal" and final federal financial status reports.

We are working toward the development of an automated system for tracking Financial Status Reports received from grantees. We expect that this system will be available for use by September 1984.

The manual system of monitoring prior year accounts until "final" will be used until the automated formula grant financial management system is implemented.

## SATELLITE CENTER FOR HEARING IMPAIRED

Question: I understand that a significant number of persons with Developmental Disabilities are also hearing impaired. I also understand that the special problems of these children are not always adequately met in special education and community service programs.

Could an additional UAF satellite center for the hearing impaired developmentally disabled group make a significant contribution to resolutions to these problems?

Answer: Our interest in improving services to the hearing impaired developmentally disabled population is long standing, but we do not believe that a satellite center solely dedicated to special problems of this group is necessary.

Although the hearing impaired developmentally disabled population is important, we believe that the interests of this group could best be served through the use of existing University Affiliated Facilities Network across the nation.

To specifically address the needs of this group, the Administration on Developmental Disabilities will survey the University Affiliated Facilities to identify those which have existing programs in this area. Rather than duplicate these programs around the country, we believe that it would be a more appropriate use of resources to designate lead University Affiliated Facilities in each region for training and service provisions.

## CONSOLIDATION OF RESEARCH AND DEMONSTRATION PROGRAMS

Question: You are proposing a new appropriation to consolidate three separate programs relating to child welfare services and research. How have the authorizing committees reacted to your plan to merge these programs through the appropriations process?

Answer: We hope to obtain approval for the consolidation. It should be noted that the funds appropriated under the consolidation of these programs would be used for the purposes specified in the authorizing legislation.

Question: By requesting an 80% reduction in funding, from the current level of $21.4 million down to $4.2 million, how can you effectively carry out the legislative mandates in these areas?

Answer: A reduction in funding means that fewer new projects will be funded and some lower priority research areas may not be included in our programs. We have been very successful in increasing the effectiveness of our research dollars through techniques such as increased grantee match and shortened project periods. We believe that we can carry out a successful research program at the reduced funding level.

Question: Specifically, what activities would be eliminated?

Answer: Since most existing projects received a one-time grant award covering project periods of twelve to eighteen months, very few projects require continuation funding. Therefore, most of the requested appropriation would be used to fund new projects, and no existing project would be eliminated. New projects would be funded in the areas authorized by the legislation.

## CONSOLIDATION OF AGING PROGRAMS

Question: You are proposing legislation to combine several programs currently authorized under the Older Americans Act, including nutrition, supportive services and centers, and State agency activities. If the Older Americans Act is simply extended in its present form, what amounts would you recommend for each of the existing categorical aging programs.

Answer: The Fiscal Year 1985 budget request for the consolidated program is the same as the amounts available in Fiscal Year 1984 less the amounts which were allotted to the Federated States of Micronesia, and the Marshall Islands (The Trust Territories of the Pacific Islands). These Territories would be funded through a compact of free association. We would recommend funding for the individual programs as follows:

|  | FY 1984 Current Estimate | FY 1985 Estimate |
|---|---|---|
| State Agency Activities | $21,673,000 | $21,598,000 |
| Supportive Services and Senior Centers | 240,869,000 | 240,362,000 |
| Congregate Nutrition Services | 321,574,000 | 320,892,000 |
| Home-delivered Nutrition Services | 62,025,000 | 61,894,000 |
| Commodities or Cash-in-lieu-of Program | 116,000,000 | 116,000,000 |
| TOTAL | $762,141,000 | $760,746,000 |

## MERGING CHILD WELFARE SERVICES AND TRAINING

Question: The fiscal year 1985 budget proposes to merge the authorities for child welfare services and child welfare training. Do you think the States would use any of their funds under this combined authority for training, or would they use it all for services?

Answer: An analysis of the fiscal year 1984 State plans indicates that thirty-two States developed plans for training agency supervisors, workers, volunteers, and paraprofessionals. One hundred-fourteen different training goals were identified. These covered a wide range of training activities including State-wide conferences and local training workshops focusing on specific services or skills for training agency staff, regional managers, and representatives from various professions, community agencies, and parent groups. Based on these plans we would fully expect that the States will carry on both the services and training.

Question: What would be the impact of this change on social work schools and other institutions that currently use child welfare training funds to support their students?

Answer: Although some schools continue to rely on child welfare funds to support degree-oriented programs, many schools have responded to the shift in program direction initiated in fiscal year 1982 which encouraged the development of in-service training for persons currently employed in child welfare, and recruitment of part-time and non-degree candidates for traineeship grants. In fiscal year 1983 nearly three times as many child welfare workers received traineeship support as degree-oriented students. If States opt to continue to use child welfare funds for training and work collaboratively with schools to structure specific training activities, the impact of the combined authorities would be minimal.

## CHILD WELFARE SERVICES AND TRAINING

Question: How soon will you submit legislation to merge the authorities of child welfare services and child training?

Answer: The "Child Welfare and Foster Care Amendments of 1983" were submitted to Congress on May 23, 1983. This proposed legislation contains a provision that would merge authority for child welfare training grants under section 426 of the Social Security Act with the basic program of State grants for child welfare services under title IV-B of the Act.

## NEWSPAPER REPORTS ON SUSPICIOUS GRANT ACTIVITIES

Question: There have been reports in the newspaper that a number of applications for discretionary grants that were ranked relatively poorly have received funding, while applications that were ranked higher did not receive funds. Are these charges true? If so, how can you justify them?

Answer: A small percent -- 3.5% -- of the funding is used to fund low ranked applications. Typically, these applications propose low cost/high risk innovative ideas that, if successful, could make major contributions to solving a specific problem. Examples of such projects are: an attempt to use an upcoming World's Fair to generate employment for inner city welfare mothers; a project to generate income for Alaskan Natives through the sale of artwork created during the winter months of inactivity. These projects were funded instead of others which may have been more highly ranked but which reflected approaches or ideas which have been applied numerous times before. It should be noted, however, that only 7% of funded projects ranked below the 50th percentile.

## PROCEDURE FOR SELECTING APPLICANTS

Question: Please describe briefly your procedure for selecting applicants to receive funding. What other factors besides the quality of the application determine whether an applicant will receive funds?

Answer: Some 3,000 preapplications are received each year and are screened by HDS staff to assure conformance with basic requirements, such as maximum length and required grantee match. Preapplications that meet all the screening requirements are scored by at least 3 field reviewers who are selected for their expertise, and who are not, in most cases, Federal employees. These reviews are organized around individual priority areas to assure competition only among similar preapplications. The results are submitted to HDS Senior Staff (the ASHDS, Program Commissioners and Staff Office Directors) who discuss preapplications individually and select approximately 500 to be invited to submit a full application.

Finalists have 35 days to submit a full application. Once received, applications are evaluated by 3 to 5 reviewers. In a few cases final applications are subjected to an administrative review by federal staff when Senior Staff decides that the concept paper is unique or exemplary. The results of this evaluation are submitted to Senior Staff who again discuss every project under consideration and make the final selection of some 200 to 225 grantees.

As with previous programs, the Coordinated Discretionary Program uses field reviews as the primary factor in a selection process that takes into account other factors such as urban/rural balance, geographic distribution and ethnic representation. Unlike the previous process, however, final decisions are made only after consultation among Senior Staff, rather than by one program official in isolation. This process -- explained in the program announcement -- promotes more informed and coordinated decisions, while assuring full discussion of every selection. HDS Senior Staff, by discussing every application, are able to apply program-wide criteria such as geographic distribution -- something which would be impossible for field reviewers since each reviewer only sees 15 to 20 applications.

The influence that reviewers' scores have on the selection process remains strong, however. Sixty-four percent of funded applicants ranked in the top 20% of reviewer scores and only 3.5% of CDP funds are used to fund projects ranking below the 50th percentile.

Question: Do regulations exist that spell out criteria to use in awarding funds under the discretionary grants program? If not, is there any other type of written guidance?

Answer: This procedure is in full compliance with existing Departmental regulations. In addition, it is explained in full detail in the program announcement published annually in the Federal Register and in the application kit used by all prospective applicants for preparing their applications to the program. It should also be noted that, aside from requiring coordination among decision makers, the procedure is almost identical to that used by HDS in the past.

## IMPROPER SITE VISITS

Question: We understand that the Discretionary Grants Program has been criticized for making unnecessary site visits to grantees, and for not visiting grantees that need help. What determines whether you will make a site visit?

Anwser: The Office of Human Development Services Grants Administration Staff Manual states that site visits are made for the purpose of reviewing the grantee's capabilities and practices for managing the grant as well as its program accomplishments. These visits are strongly encouraged and, in fact, the Manual indicates site visits should be made to each grantee at least annually, depending upon the availability of resources. It further states that priority should be given in making site visits to "high risk grantees known to be encountering problems and to new grantees." The timing of the site visit is to be based on such factors as the need for background information prior to refunding a grantee or for verifying that special conditions, audit recommendations, previous deviations or problems have been corrected. This guidance is used in determining the need for a site visit.

Question: Is there written guidance on this?

Answer: Yes. The Office of Human Development Services Grants Administration Staff Manual provides written guidance on site visits in Chapter 11, Post Award Project Administration.

Question: How much has been spent on site visits under the Discretionary Grants Program?

Answer: As a matter of budgetary restraint, we have reduced our overall travel budget. We have, however, instituted procedures that have increased the quality of our project monitoring. In addition, the existing travel budget is adequate to conduct site visits when conditions warrant it. Specific information on how much has been spent on site visits under the Coordinated Discretionary Program, however, is not available.

Question: How much do you expect to spend this year?

Answer: The Coordinated Discretionary Program has been extremely successful in correcting many of the grants administration deficiencies that the Inspector General found were common prior to 1980. Implementation of an automated grants reporting system to identify grantees with possible problems also has made it easier to target services on those grantees most in need of a site visit. However, since specific information on how much has been spent on site visits to grantees funded under the Coordinated Discretionary Program is not available for previous years, it is difficult to project the amount for this year.

## RUNAWAY YOUTH PROGRAM

Question: The Runaway Youth program has been funded at over $20 million for two fiscal years. Why are you requesting half this amount for fiscal year 1985?

Answer: The problem of runaway and homeless youth is one which is primarily a community problem which is, and should be, treated first and primarily with State and local resources. About 73 percent of those served by our runaway centers are from the immediate community. Census data indicate that the number of children in the prime runaway age groups will continue to decline. This in turn should reduce the number of runaways seeking services.

The funding level of $10.5 million is adequate to insure that centers are available in every State for runaway and homeless youth. These resources will be used to support the best approaches in each State, as opposed to providing ongoing funding for the same centers year after year.

Funding for centers will be awarded for one year periods, with centers competing annually for new awards. This approach, used in fiscal years 1983 and 1984 for all centers except a few which received initial funding under the Act in fiscal year 1981, has led to minimal reliance by most centers on funding from the Office of Human Development Services. On average, each receives only 25 percent of its total budget from the Runaway and Homeless Youth Program, and uses these dollars to lever extensive support from State, local and other sources.

Question: What would be the effect of such a funding reduction on the shelters supported under the program?

Answer: Since Runaway and Homeless Youth Act funds account on the average for only about 25 percent of the funding of those centers which do receive these grants, we expect these centers to continue in fiscal year 1985. One of the criteria for selection as a new grantee in fiscal years 1983 and 1984 is the ability of the grantee to access funding from other sources after the Federal grant period expires.

Question: Why, when the General Accounting Office pointed out funding inadequacies in the Runaway Youth Program, are you proposing such a dramatic funding cut for this program?

Answer: We have given a high priority to implementing the GAO recommendations. However, we believe that financial support of centers for runaway and homeless youth is primarily a local-State responsibility. The GAO found, for example, that 75 percent of the runaway youth stayed within a local or State geographic area.

We would like to emphasize that we strongly believe in the benefits to be derived from consolidation of these programs. The consolidation would allow the States more flexibility in the use of Title III funds and reduce burdensome accounting and administrative processes and paper- work. The consolidation would expand the provisions of the 1978 and 1981 amendments to the Act which provided the States and area agencies with the flexibility to address the specific issues and concerns of individuals in their jurisdictions.

## NATIONAL LEGAL SERVICES PROJECTS

Question: The Appropriations Committee Report accompanying the regular Fiscal Year 1984 Labor-HHS bill directed you to fund national legal services projects at least at the Fiscal Year 1981 spending level. The words "spending level" were used so that there would be no confusion that the Committee intended to maintain the Fiscal Year 1981 program level. How much was actually spent during Fiscal Year 1981 for national legal services projects?

Answer: From the amounts appropriated in Fiscal Year 1981 for Title IV of the Older Americans Act, $388,890 was obligated for national legal services projects.

Question: How much do you intend to spend for national legal services projects in Fiscal Year 1984?

Answer: Final decisions on individual projects to be funded in Fiscal Year 1984 have not been made. Therefore, at this time, we cannot provide information on the total funding for national legal services projects.

Question: How much is in your Fiscal Year 1985 budget for such projects?

Answer: Decisions on the specific programs to be funded in Fiscal Year 1985 have not been made.

## CUT IN HUMAN RESOURCES RESEARCH AND DEMONSTRATION PROJECTS

Question: The Administration is requesting a total of $4.5 million to fund human resources research and demonstration programs that this year are receiving $21.4 million -- a decrease of over 75 percent. How can your research and demonstration programs function effectively with such limited funding?

Answer: A reduction in funding means that fewer new projects will be funded and some lower priority research areas may not be included in our programs. We have been very successful in increasing the effectiveness of our research dollars through techniques such as increased grantee match and shortened project periods. We believe that we can carry out a successful research program at the reduced funding level.

Question: What types of projects do you expect to fund with this $4.5 million?

Answer: New projects would be funded in the areas authorized by the legislation, including child welfare, adoption opportunities, child abuse and neglect, and social services.

Question: What projects will be dropped?

Answer: No existing project would be eliminated.

Question: How will you decide what projects to continue and what to drop?

Answer: Since most existing projects received a one-time grant award covering project periods of twelve to seventeen months, very few projects require continuation funding. Therefore, most of the requested appropriation would be used to fund new projects.

## REGIONAL RESOURCE CENTERS

Question: How much is being spent to support regional resource centers for children and youth in fiscal year 1984?

Answer: There are no funds being spent for these centers in fiscal year 1984.

Question: What are your plans for these centers in fiscal year 1985?

Answer: The Administration for Children, Youth and Families does not plan to fund the regional centers in fiscal year 1985.

Question: What Federal appropriation would be necessary to continue these centers at their current level throughout fiscal year 1985?

Answer: In fiscal year 1983, the last year in which funds were awarded to regional resource centers, the grants totalled $3,500,000.

## AGING RESEARCH

Question: How much money will be required in Fiscal Year 1985 to continue on-going aging research projects at their current level?

Answer: Final decisions on individual projects to be funded in Fiscal Year 1984 have not been made. Therefore, at this time, we do not know the total funding for research in Fiscal Year 1984, nor the amounts required to maintain that level in Fiscal Year 1985.

Question: Provide for the record a list of all projects currently being funded, and amounts provided in each of Fiscal Years 1981, 1982, 1983, and 1984.

Answer: The following is a list of research projects funded to date in Fiscal Year 1984:

| TITLE/GRANTEE | AWARD NUMBER | AMOUNT |
|---|---|---|
| Wayne State University, "Developing an Index of Elder Abuse" (9.3) | 90AR0040<br>3792 | $101,943 |
| Planning Study - Technology and Commercialization of Products for the Aging | 698557 | 8,500 |
| TOTAL | | $110,443 |

The project at Wayne State University received $153,742 in Fiscal Year 1982. The Planning Study is a new project in Fiscal Year 1984.

Final decisions on individual projects to be funded in Fiscal Year 1984 have not been made. Therefore the list of projects funded to date is short. The following is a list of research projects funded in Fiscal Year 1983 and the amounts the projects received in Fiscal Years 1981 and 1982.

| TITLE/GRANTEE | AWARD NUMBER | AMOUNT AWARDED | DATE |
|---|---|---|---|
| Bureau of Social Science Research, Washington, D. C. (2.3), "A Data Archive, Analysis Center and Technical Assistance Network" | 900J1007 | $76,911 | FY 83 |
| Center for Health and Social Services Research, Inc., Pasadena, California, "Social Services Information System"(3.1) | HDJA 3439<br>90PD10044<br>(10044A) | 36,772 | FY 83 |

| | | | |
|---|---|---|---|
| Center for the Partially Sighted, "Older Partially Sighted Volunteers Advocates and Community Counselors in a Rehabilitation Program for the Visually Impaired", Santa Monica, California (6.1) | HDJA4537<br>90AR0047A | $72,805 | FY 83 |
| Coalition of Hispanic Mental Health and Human Services Organizations, Washington, D.C., "A Synthesis and Dissemination of Urban and Rural Programs Utilizing Volunteers in Service to the Hispanic Elderly" (6.1) | 90OJ1008 | 28,024<br>55,000 | FY 83<br>FY 82 |
| New York City Voluntary Action Corporation, "Computer Network on Volunteerism for New York City" (6.1) | 90OJ2002<br>HDJA 3109 | 10,000 | FY 83 |
| "A Model for Innovative Home Equity Conversion," Bureau of Maine's Elderly Affairs (6.2) | 90AR0043<br>4117 | 1,520<br>150,771 | FY 83<br>FY 82 |
| "Continuum of Long-term Care: Health Care for the Elderly," Gerontological Society | 90AR0002 | 19,999<br>85,000<br>113,525 | FY 83<br>FY 82<br>FY 81 |
| University of Michigan, National Data Archives, "Supporting Facilities for Research and Policy Development and Evaluation in the Field of Aging" | 90A1279 | 20,000<br>399,317<br>251,952 | FY 83<br>FY 82<br>FY 81 |
| Consumer Guidebook to Housing for Older Persons (AoA/HUD) | 432444<br>SA-83-3066 | 7,000 | FY 83 |
| Home Equity Training Project, National Center for Home Equity Conversion, Madison, Wisconsin (1.1) | CDP0086<br>90AR0051 | 147,000 | FY 83 |
| "The Development of an End Product Oriented Resource Targetting Model," University of Oklahoma, Health Sciences Gerontology Center (1.3) | CDP1883<br>90AR0050 | 54,509 | FY 83 |
| Hampton Institute, "Triad with Youths, Elderly," Hampton, Virginia (1.3) | CDP1063<br>90CJ0061 | 10,000 | FY 83 |
| "Interactive Model of Community Adjustment for Home-based Developmentally Disabled Adults," University of Maryland (1.3) | CDP0576<br>90DJ0017 | 70,000 | FY 83 |
| Commissioner of Human Services, Monroe County, Rochester, New York, "Use of Management Information Systems" (2.1) | CDP0415<br>90OJ1021 | 50,000 | FY 83 |
| Office of Client Information Systems, Florida Department of Health and Rehabilitation Services (2.1) | CDP2577<br>90OJ2005 | 21,870 | FY 83 |
| New York City Partnership, Inc., "Applying Business Management Techniques to Improve Shelter Program for Homeless" (2.2) | CDP0283<br>90OJ1013 | 60,000 | FY 83 |

| | | | |
|---|---|---|---|
| Illinois Department on Aging, Division of Long-term Care, "Impact of Fee Imposition on In-home Care Services for the Elderly" (2.3) | CDP2275<br>90AR0048 | 32,226 | FY 83 |
| Wisconsin Department of Health and Social Services,"Community Integration Program Evaluation," Madison, Wisconsin (2.3) | CDP1471<br>90DJ0010 | 23,271 | FY 83 |
| Juarez and Associates, "Marketing Approach to Dissemination of Management Information to Community-based Organizations" (2.6) | CDP1862<br>90NJ0007 | 30,000 | FY 83 |
| Tule Tribal Council, Porterville, California (2.7) | CDP0073<br>90NJ0004 | 40,000 | FY 83 |
| TOTAL | | $811,907<br>$690,088<br>$365,477 | FY 83<br>FY 82<br>FY 81 |

## CHILD ABUSE STATE GRANTS

Question: Why are you not requesting increased funding for child abuse State grants, when reported cases of child abuse are increasing?

Answer: The Federal government will assist States in maintaining current services through funds made available under the Social Services Block Grant Program (Title XX) and the Child Welfare Services Program (Title IV-B) of the Social Security Act. The $6,720,000 made available to the States under the Child Abuse and Neglect State Grants Program is not used to provide ongoing support or maintenance of current agency programs for which the Title XX and Title IV-B funds are used. Consistent with the Child Abuse Prevention and Treatment Act funds awarded under the Act are to be used for specific developmental or startup activities usually no longer than three years in duration for any new initiative. At the end of that period the State is expected to use its next award for another new initiative. Finally, the successful maintenance of current services will depend upon local, State, as well as Federal financial assistance to meet the continuing demand for services to prevent and treat abused and neglected children and their families.

Question: Do you plan to request supplemental funding for child abuse State grants after Congress has reauthorized the program at higher levels?

Answer: No, we do not plan to request supplemental funding for the Child Abuse State grants.

## CHILD ABUSE CENTERS

Question: How will the broadened mission of the Child Abuse Prevention and Treatment Act in pending legislation affect the work load and staffing at the National Center on Child Abuse and Neglect?

Answer: We do not believe that the broadened mission of the Child Abuse Prevention and Treatment Act in pending legislation will have a significant effect upon the workload and staffing levels of the National Center on Child Abuse and Neglect. We believe it will be possible to absorb the impact of any pending legislative changes. If it appears that this is not the case, we will review the situation and take appropriate action.

Question: Will it result in a lessening of attention to the Center's existing mission?

Answer: We do not believe that staff attention will be diverted from the National Center's existing mission if the Child Abuse Prevention and Treatment Act's mission is broadened. If it appears that this is not the case, we will review the situation and take appropriate action.

Question: What percent of the National Center's resources will be required to carry out this new mission?

Answer: The bills now before the two Houses differ in content and in the presumed location of new or enlarged responsibilities. Until a law is passed, we cannot estimate the effect of a broadened mission.

Question: Since the National Center will be expanding its mission, why are you requesting the same level of funding that the Center has had for the last four years?

Answer: Funds requested for the National Center are awarded to States to begin new activities or support changes and improvements in services. They do not generally support ongoing programs. States will therefore be responsible for shifting their support to new areas described by a broadened mission for the National Center.

## CHILD WELFARE DATA COLLECTION

Question: How many of the 273,000 children reported to be in substitute care are being supported by the IV-E foster care program? How many by the Federal child welfare services program? How many with other Federal funds? (If the answer is unknown), why is it that we still don't have this information?

Answer: States reported during FY 1982 on the Quarterly Statement of Expenditures for Foster Care and Adoption Assistance an average monthly caseload of 102,000 children being supported by the Title IV-E foster care program. Currently there is no data available to ascertain how many of the 273,000 children reported to be in substitute care are being supported by the Federal child welfare services program, or other Federal funds. We are looking at the problems which make it difficult to obtain this information, such as service definitions and definitions of who should be included in the population so that this information could be collected in the future.

Question: How many children are placed for adoption each year in the U.S.? How many children are currently free for adoption? (If the answer is unknown), why don't we have this information?

Answer: A study by the American Public Welfare Association (APWA) indicates that approximately 43,000 children in substitute care are free for adoption. The same study indicates that approximately 24,000 children had their adoption finalized during the one year reporting period.

Question: How much did the study, "Characteristics of Children in Substitute and Adoptive Care" cost? How long did it take to complete? Why wasn't it designed to get hard data on the number of children being served by Federal and State adoption and foster care programs.

Answer: "The Characteristics of Children in Substitute and Adoptive Care" emanated from the Voluntary Cooperative Information System (VCIS) grant that HDS awarded to APWA. The cost of this study was $40,000. The data collection started in December 1982 and the study was published in December 1983. Thus its duration was one year. This year's study is expected to be completed within 9 months with a final report being published in December 1984 at a projected cost of $45,000. Our experience with previous voluntary data collection activities that we funded, indicated that such methods yield very reliable data with high response rates.

Question: Why was the participation of the States in "Characteristics of Children in Substitute and Adoptive Care" voluntary? Which States did not participate? Why? What effect did the non-participation of these States have on the Study's usefulness?

Answer: Our previous experience indicated that voluntary data collection activities developed by the States for their management purposes produces highly reliable data bases with high rates of participation. This was verified by the results of the national Child Welfare Indicators Survey (CWIS) and by the fact that only three States did not participate. These were Alaska, Indiana, and New Jersey. Alaska had a small staff that was unable to handle such a comprehensive data gathering activity. Indiana indicated that their Statewide Child Welfare Information System was not operational statewide at that time so they were unable to participate. However, the system was finally implemented on October 1, 1983, thus Indiana will participate in the current child welfare study. New Jersey was undergoing a major reorganization at that time and declined to participate. Their status for the current study is still uncertain. The non-participation of these three States had no effect on the study's usefulness since other available data from these States was used to make national estimates.

Question: Was "Characteristics of Children in Substitute and Adoptive Care" a one-time study, or are there plans to collect these data on a regular basis? If not, why not?

Answer: "Characteristics of Children in Substitute and Adoptive Care" will be an on-going study. The data collection for this year's study is currently underway and the final report will be published no later than December 1984.

Question: Section 476 of the Adoption Assistance and Child Welfare Act authorizes the Secretary to require States to submit information on children receiving adoption or foster care services any time the Secretary my choose. Why haven't you acted on this authority to get yearly data?

Answer: We have been successful with our voluntary approach for collecting child welfare data. This method has resulted in reliable national estimates with a high State participation rate. Therefore, with these satisfying results we do not perceive a need to invoke the authority of Section 476 of the Adoption Assistance and Child Welfare Act.

## CONSOLIDATION OF TITLE III SERVICES AND ADMINISTRATION

Question: Under the Administration's Title III proposal, funds for State Agency Administration would be included in the consolidated grant. Do you think it is likely that States would use more funds for State administration and that less would be available for services?

Answer: States currently have the authority to transfer up to three-fourths of one-percent of the funds received for Supportive Services and Senior Centers, Congregate Nutrition Services, and Home-delivered Nutrition Services for State Agency Activities. Similarly, States have the authority to transfer funds from the State Agency Activities allotment to the services allotments if they determine that funds are not required for State Agency Activities. In Fiscal Year 1983, States opted to transfer funds as follows:

- o Two States reduced their allotments for State Agency Activities by transferring funds to other accounts.
- o Twenty-one States transferred funds to State Agency Activities. Increases in allotments ranged from $10,166 to $368,612.

States have been using the existing transfer authority responsibly; we assume that they will continue to do so.

Question: Under your proposal would there be a limit on the amount of funds that could be used for administration?

Answer: The legislative proposal submitted to Congress does not establish a limit on the amounts to be used for State Agency Activities.

## FUNDS FOR MEALS

Question: To what factors do you attribute the projected meals increase if total Federal funding remains the same?

Answer: The increase in the number of services supported, including meals, results from a projected increase in the return on Federal investment of 8% and a projected level of only 5.4 percent for inflation. Of the 8% improvement in Federal investment, approximately 5.4 percent will replace meals and other services which we would not have been able to support without increased efficiency and a higher return on Federal investment, and 2.6 percent will produce additional services and meals.

Question: Are you expecting that there will be an increase in amounts older persons contribute toward the cost of meals?

Answer: Yes, part of the projected increase in the return on Federal investment results from an increase in program income.

Question: What is the projected level of increase in the amount of these contributions?

Answer: In Fiscal Year 1983 the per meal contribution was 51¢. We are projecting per meal contributions of 53¢ in Fiscal Year 1984 and of 55¢ in Fiscal Year 1985.

Question: Are you assuming that there will be an increase in State or local funds to support an increased number of meals?

Answer: No, we are not assuming an increase in State or local funds to support an increase in the number of meals.

## PROPOSAL TO TRANSFER COMMODITIES OR CASH-IN-LIEU-OF PROGRAM

Question: Why is the Administration proposing this transfer when it has been rejected by Congress repeatedly in the past?

Answer: The consolidation would allow the States more flexibility in the use of funds and reduce burdensome accounting and administrative processes and paperwork. If this part of the program were administered by the Administration on Aging, States would no longer have to coordinate activities under the Older Americans Act with the Department of Agriculture. The Administration on Aging would then be the only Federal contact. We are committed to returning management of the Title III programs to State and local levels. Therefore, we have proposed this transfer in Fiscal Year 1985.

Question: Under this proposal would the States receive a hold harmless amount, for example an amount equal to what they received from USDA in Fiscal Year 1984?

Answer: Yes. The legislative proposal includes a provision that would ensure that States would receive in Fiscal Year 1985 at least the amount they received in Fiscal Year 1984 for this program.

## EXPANDED MANAGEMENT INITIATIVES BY THE ADMINISTRATION ON AGING

Question: Other than initiatives to increase the level of program income from contributions of older participants for service, what kind of management initiatives will the Administration on Aging be undertaking?

Answer: The Administration on Aging will continue to expand management improvement initiatives instituted in Fiscal Year 1983 to increase service levels. Current efforts are aimed at uniform implementation of processes throughout the aging network which increase program income, improve accountability for such funds, improve financial management of the programs, and, as a result, increase the return on investment of Federal funds.

Question: How will you "increase the return of Federal investment of Title III appropriations" as is referred to in the Administration on Aging budget justifications?

Answer: The assumption that the return on Federal investment can be improved is based on recent history. In Fiscal Year 1980, the return on Federal investment in the Nutrition Program was 1.90. That is, the Federal government had to invest $1.90 in programs under Part C of the Older Americans Act to produce a meal. In Fiscal Year 1983, the return on Federal investment in the Nutrition Program was 1.77. Inflation ranged from 7 to 9 percent per year during this time. Yet, the return on Federal investment improved during this time. Using Fiscal Year 1980 as a base, after inflation, the return on Federal investment in Fiscal Year 1983 should have been 2.36. Not only have the programs been able to mitigate the impact of inflation, but they have further reduced the Federal funds required to produce a meal. In Fiscal Year 1981 the return on Federal investment improved by 10.5%, in Fiscal Year 1982, by 11.3%, and in Fiscal Year 1983, by 7.8%. We are confident that a rate of improvement of 8 percent can be maintained during the next two fiscal years if measures that have been instituted in some but not all programs are adopted nationally.

Current efforts are aimed at uniform implementation of processes throughout the aging network which increase program income, improve accountability for such funds, improve financial management of the programs, and as a result increase the return of investment of Federal funds.

## SHIFT OF FUNDS FROM CONGREGATE NUTRITION SERVICES

Question: In Fiscal Year 1983 States shifted over $38 million from the congregate program to other service categories. To what do you attribute this trend?

Answer: As a result of transfers in Fiscal Year 1983, the amounts available for Congregate Nutrition Services were decreased by $38,360,465. The amounts available for State Agency Activities were increased by $2,266,264; the amounts available for Supportive Services and Senior Centers were increased by $18,280,831; and the amounts available for Home-delivered Nutrition Services were increased by $17,813,370. Among the reasons for these transfers may be that while the Congress provided an increase of $32,325,000 for Congregate Nutrition Services and of $4,675,000 for Home-delivered Nutrition Services in Fiscal Year 1983, there has been no increase in funds for Supportive Services and Senior Centers in recent years. The aging population is growing older. As the age of the older population grows, there is an increase in the need for supportive services such as in-home services and for home-delivered meals. Further, a recent evaluation of the Nutrition Program concluded that many of the older persons that were being served when the program was first instituted have grown older and need home-delivered meals, thus increasing the need for Home-delivered Nutrition Services.

Question: If States are increasingly shifting funds from Congregate Nutrition Services, does this mean that this program is overfunded, or that other Title III service categories are underfunded in relation to the need or demand for these services?

Answer: No. The shift in funds reflects States use of this transfer authority in order to fund services according to the needs and priorities of the individual States and localities. The 1981 Amendments to the Older Americans Act authorized States to transfer up to 20% of the funds allotted for Supportive Services and Senior Centers and Nutrition Services.

## EVALUATION SET-ASIDE FROM OLDER AMERICANS ACT FUNDING

Question: Can you provide the Committee with the amount of funds which have been set aside for program evaluation for the last four fiscal years, the program account from which funds were taken, and a detailed description of how these funds were used?

Answer: The information on funds used for evaluations follows:

FISCAL YEAR 1980

| | |
|---|---|
| Source: | |
| Supportive Services and Senior Centers | $1,663,838 |
| Congregate Nutrition Services | 2,279,250 |
| Home-delivered Nutrition Services | 500,000 |
| Training, Research, and Discretionary Projects and Programs | 614,260 |
| TOTAL | $5,057,348 |
| Use: | |
| Title IV--- | |
| Long-term Care Channeling Agency Evaluation | 614,260 |
| Sub-total, Title IV | 614,260 |
| Title III--- | |
| Long-term Care Channeling Agency Evaluation | 1,800,000 |
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation | 919,000 |
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation (State Reform Demonstration Project) | 51,255 |
| Title IV-A Evaluation | 2,000 |
| Differences in Needs and Services Programs between the Rural and Urban Elderly | 258,000 |
| Congregate Housing Services Program | 500,000 |
| Evaluation of Advocacy Programs Funded under Title III | 353,856 |
| Population Estimates of Persons 60+ | 4,000 |
| Program Costs | 11,681 |
| Location of Nutrition Sites Relative to Concentration of low-income and Minority Elderly | 50,511 |
| Findings Regarding Rural Elderly | 4,960 |
| Federal Council on Aging Mandated Studies: | 478,416 |
| Community Service System Development | (153,000) |

| | |
|---|---|
| Identifying those Elderly in Greatest Need of Older Americans Act Programs | (100,000) |
| Low-income and Minority Groups Participation in Programs under the Older Americans Act | (50,000) |
| Fundamental Purposes and Effectiveness of Title V Programs | ($100,000) |
| Other | (75,416) |
| Area Agency | 4,950 |
| Lapsed | 4,459 |
| Sub-total, Title III | 4,443,088 |
| TOTAL | $5,057,348 |

## FISCAL YEAR 1981

| Source: | |
|---|---|
| Supportive Services and Senior Centers | 318,083 |
| Congregate Nutrition Services | 959,327 |
| Home-delivered Nutrition Services | 255,598 |
| TOTAL | $1,533,008 |

| Uses: | |
|---|---|
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation | 1,057,455 |
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation (State Reform Demonstration Project) | 10,200 |
| Assessment of Adequacy of In-home Services | 125,000 |
| Plight of Elderly Residents in Rural Areas | 75,000 |
| Evaluability Assessment of the Title VI Program | 4,550 |
| Use of Senior Community Service Employment Program Funds by States | 9,000 |
| State Education and Training Program | 180,000 |
| Analysis of Use and Costs of Veterans Administration Hospitals Based Home Care | 50,000 |
| Program Costs | 1,813 |
| Lapsed | 19,990 |
| TOTAL | $1,533,008 |

## FISCAL YEAR 1982

| Sources: | |
|---|---|
| Supportive Services and Senior Centers | 593,053 |
| Congregate Nutrition Services | 2,461,651 |
| Home-delivered Nutrition Services | 573,500 |
| National Clearinghouse on Aging | 790,876 |
| TOTAL | $4,419,080 |

| Uses: | |
|---|---|
| LTC Channeling Evaluation | 3,200,000 |
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation | 1,037,900 |
| Title VI Evaluation | 153,620 |
| Miscellaneous | 26,249 |
| Lapsed | 1,311 |
| TOTAL | $4,419,080 |

FISCAL YEAR 1983

| | |
|---|---|
| Source: | |
| Congregate Nutrition Services | 1,199,779 |
| Training, Research, and Discretionary Projects | 1,890,000 |
| TOTAL | 3,089,779 |
| Uses: | |
| Title IV--- | |
| LTC Channeling Demonstrations | $1,890,000 |
| Sub-total, Title IV | 1,890,000 |
| Title III--- | |
| Evaluations carried out by the Assistant Secretary for Planning and Evaluation | 1,199,779 |
| Sub-total, Title III | 1,199,779 |
| TOTAL | $3,089,779 |

## FUNDING FOR SENIOR CENTERS

Question: Can you estimate how much Title III funding is being used by States and area agencies on aging for senior centers?

Answer: Based on information collected through the National Data Base on Aging, Federal and non-federal funds expended for the renovation, alteration, acquisition, and construction of Senior Centers are estimated to be $40,000,000.

Question: What priority is given by States to funding senior centers?

Answer: Amounts awarded for Supportive Services and Senior Centers are used by State and area agencies to fund those items which respond to the service needs of older persons in the particular jurisdiction. Each locality determines the requirements for senior centers and funds those according to priority and need.

## COST OF MEAL SERVICES

Question: Can you provide projections as to the cost per congregate and home-delivered meal for Fiscal Year 1985? Show the cost, cost for food, management, and supportive services associated with the provision of nutrition services if possible.

Answer: The Administration on Aging no longer collects information on the separate costs associated with a meal: food costs, management, and supportive services. Further, during the Fiscal Year 1985 budget process the method through which meals are estimated has been changed from estimates based on meal costs to estimates based on the return on Federal investment. Another change was to include all meals in budget estimates. Previously, we had included only meals generated from Title III-C funds, the entitlements under the Commodities or Cash-in-lieu-of Program, and matching funds. Briefly stated, the return on Federal investment reflects the Nutrition Services investment (exclusive of funds transferred out by the States and of funds reserved for evaluations) required to produce a meal.

Recent return on Federal investment factors and projections are as follows:

| | Return on Federal Investment | Improvement (after inflation) |
|---|---|---|
| o Fiscal Year 1980 | 1.90 | |
| o Fiscal Year 1981 | 1.86 | 10.5% |
| o Fiscal Year 1982 | 1.79 | 11.3% |
| o Fiscal Year 1983 | 1.77 | 7.8% |
| o Fiscal Year 1984 | 1.70 | 8.0% |
| o Fiscal Year 1985 | 1.65 | 8.0% |

Question: What is the range of meal costs in all States?

Answer: In Fiscal Year 1983, the return on Federal investment in the States was as follows:

| | |
|---|---|
| Alabama | 1.769 |
| Alaska | 6.226 |
| Arizona | 1.769 |
| Arkansas | 1.111 |
| California | 2.159 |
| Colorado | 1.764 |
| Connecticut | 1.780 |
| Delaware | 2.070 |
| District of Columbia | 2.361 |
| Florida | 1.834 |
| Georgia | 2.149 |
| Hawaii | 1.317 |
| Idaho | 1.864 |
| Illinois | 1.964 |
| Indiana | 1.683 |
| Iowa | 1.433 |
| Kansas | 1.344 |
| Kentucky | 1.696 |
| Louisiana | 1.127 |
| Maine | 2.050 |
| Maryland | 1.653 |
| Massachusetts | 1.761 |
| Michigan | 1.469 |
| Minnesota | 1.627 |
| Mississippi | 1.277 |
| Missouri | 1.595 |
| Montana | 1.357 |
| Nebraska | 1.480 |
| Nevada | 1.986 |
| New Hampshire | 1.651 |
| New Jersey | 2.268 |
| New Mexico | 1.186 |
| New York | 1.435 |
| North Carolina | 1.921 |
| North Dakota | 1.645 |
| Ohio | 2.374 |
| Oklahoma | 1.410 |
| Oregon | 1.690 |
| Pennsylvania | 2.471 |
| Rhode Island | 1.813 |
| South Carolina | 2.002 |
| South Dakota | 1.926 |
| Tennessee | 1.920 |
| Texas | 1.591 |
| Utah | 1.418 |
| Vermont | 2.548 |
| Virginia | 2.726 |
| Washington | 2.029 |
| West Virginia | 1.797 |
| Wisconsin | 1.226 |
| Wyoming | 2.144 |
| American Samoa | 2.372 |
| Guam | 2.774 |
| Puerto Rico | 1.733 |
| Trust Territory of the Pacific Islands | 3.287 |
| Virgin Islands | 4.731 |
| Northern Mariana Islands | 3.247 |
| TOTAL | 1.773 |

## PROPOSED REDUCTION IN AGING DISCRETIONARY PROGRAM

Question: The Administration on Aging Fiscal Year 1985 budget for discretionary research, training, and demonstration programs proposes a sharp decrease in funds as compared to the Fiscal Year 1984 levels--from over $22 million to $5 million. What currently funded activities would be continued under such a decreased funding level?

Answer: Decisions on the specific activities to be funded in Fiscal Year 1985 have not been made. Therefore, we do not have information on the activities which would be funded. The Administration on Aging expects to fund projects in those areas of highest priority.

Question: What specific activities would be terminated?

Answer: Decisions on the specific activities to be funded in Fiscal Year 1985 have not been made. Therefore, we do not have information on the activities which would be funded or those which would be terminated, if any. The Administration on Aging expects to fund projects in those areas of highest priority.

Question: How much funding would be allocated for legal services programs for the elderly?

Answer: Final decisions on individual projects to be funded in Fiscal Year 1985 have not been made. Therefore, at this time, we cannot provide information on the total funding for legal services projects.

Question: How would you maintain support for in-service training of State and area agency personnel?

Answer: Final decisions on individual projects to be funded in Fiscal Year 1985 have not been made. Therefore, at this time, we cannot provide information on the total funding for in-service training of State and area agency personnel.

Question: If the budget were reduced to this proposal level, what impact would this have on the Administration on Aging personnel currently involved in administering the discretionary programs?

Answer: The assignment of staff with primary responsibility for administering the discretionary programs would be re-examined and appropriate adjustments made.

Question: How many Federal level personnel are currently assigned to the administration of Title IV discretionary programs (including the Administration on Aging and Office of Human Development Service staff)?

Answer: There are currently fifty persons employed in the Administration on Aging who are assigned to the Title IV program. There are staff in OHDS assigned to work on issues related to aging. However, no one person, other than Administration on Aging staff is assigned to work solely on the administraion of Title IV discretionary programs.

## UTILIZATION OF FUNDS FOR RESEARCH, DEMONSTRATION, AND TRAINING

Question: The appropriations level for Title IV research, demonstrations and training programs on aging has remained constant at $22.175 million since Fiscal Year 1982. For the record supply a detailed breakdown of the amount of funding for various programs by major category under Title IV from Fiscal Year 1982 through Fiscal Year 1984. Include in the breakdown minimally the following categories: education and training (State education and training and career preparation), multidisciplinary centers of gerontology, long-term care channeling demonstrations (showing funds for both the demonstrations and evaluation components), legal services, demonstrations (showing this by major sub-category), research (showing this by major sub-category), and minority organizations.

Answer: The information on use of Title IV funds follows:

| | FY 1982 | FY 1983 | FY 1984 TO DATE |
|---|---|---|---|
| Education and Training | | | |
| State Education and Training | $3,588,730 | $2,244,009 | $4,188,730 |
| Career Preparation | 2,766,263 | 2,452,106 | |
| Grants Resulting from the 1983 OHDS Competition | | 53,764 | |
| Other Training | 1,919,226 | 801,956 | 13,500 |
| Multidisciplinary Centers of Gerontology | | | |
| Long-term Care Gerontology Centers | 3,161,926 | 2,718,065 | 2,137,487 |
| National Policy Study Centers | | 803,650 | 531,495 |
| Long-term Care Channeling Demonstrations - Evaluation | | 1,890,000 | |
| Legal Services | 572,670 | 371,893 * | |
| Demonstrations | | | |
| Legal, Protective and Ombudsman Services Developers | 2,852,000 | 2,852,020 | |
| National Impact | 856,377 | 1,227,937 | 217,938 |
| Grants Resulting from the 1982 OHDS Competition | 2,380,034 | 1,224,191 | 94,384 |
| Grants Resulting from the 1983 OHDS Competition | | 1,919,812 | 314,786 |
| Disaster Assistance | 81,500 | 65,315 | 55,000 |
| Other | 1,471,421 | 1,570,583 | 88,551 |
| Research | | | |
| Grants Resulting from the 1982 OHDS Competition | 937,279 | 226,032 | 101,943 |
| Grants Resulting from the 1983 OHDS Competition | | 538,876 | |
| Other | 715,796 | 46,999 | 8,500 |
| Minority Organizations | 846,343 | 1,166,212 | 105,508 |
| TOTAL | $22,149,565 | $22,173,420 | $7,857,822 |

* Excludes $194,655 included under Career Preparation, total funding for Legal Services is $566,548.

## COORDINATION WITH OTHER FEDERAL AGENCIES

Question: How does the Administration on Aging assure that its funds under the Title IV discretionary research, demonstration, and training program are not duplicative of such activities conducted by other Federal agencies?

Answer: The Administration on Aging is involved in a number of activities which involve coordination with other Federal agencies and which help in avoiding duplication. The Commissioner on Aging serves on the National Advisory Council on Aging, the Inter-agency Committee on Handicapped Research, and other oversight committees where ideas and plans are shared. Staff serve on sub-committees and exchange solicitations and lists of funded applications. Staff of other Federal Agencies (for example, the National Institute on Aging, the National Institute on Mental Health, the Veterans Administration, and the Department of Housing and Urban Development) serve on grant review panels which involve aging issues.

## PERSONS TRAINED UNDER OLDER AMERICANS ACT TITLE IV PROGRAMS

Question: The OHDS Budget Justifications indicate that an estimated 29,000 students have been trained in academic aging programs funded under the Title IV training program. Your budget proposes to reduce the entire Title IV program, including not only training, but also research and demonstration programs, from over $22 million to $5 million. Can you estimate how many of those persons trained have actually worked, or are currently working in the field of aging?

Answer: The Administration on Aging does not have information on how many of the 29,000 students trained under the Title IV programs are actually working in the field of aging.

Question: What priority would the Administration give to continuation of training programs if the budget were reduced as you propose?

Answer: Final decisions on individual programs to be funded in Fiscal Year 1985 have not been made. The Administration proposes to fund those programs with the highest priority.

Question: How much of the $5 million would be used for training programs?

Answer: Final decisions on individual programs to be funded in Fiscal Year 1985 have not been made. Therefore, at this time, we cannot provide information on funding for training programs.

## GRANTS TO INDIANS

Question: The Administration budget proposes to increase the grant program for older Indians under Title VI of the Older Americans Act from $5.7 million to $7.5 million. This increase would allow the Administration on Aging to increase by 27 the number of Tribal organizations funded--from 83 to 110 Tribes. The budget justifications indicate that the policy established for Title VI originally was to create a stable funding source for older Indians which would support a service delivery system for Indians comparable to services for other older persons under Title III. Is this policy still in effect?

Answer: Yes. The policy continues to focus on treating the Title VI program as a stable funding source which supports a service delivery system approach comparable to Title III.

Question: If so, what progress has been made in achieving this goal?

Answer: One measure of how this goal is accomplished are the types of services provided to older Indians under Title VI. The following is a list of services provided under Title VI with funding provided in Fiscal Year 1982:

(Times services were provided))

| | |
|---|---|
| **Access Services** | |
| Information & Referral | 103,802 |
| Transportation | 348,071 |
| Other | 63,766 |
| **Community-based Services** | |
| Legal | 5,933 |
| Other | 56,412 |
| **In-Home Services** | |
| Homemaker | 10,018 |
| Other | 16,958 |
| **Nutrition Services** | |
| Meals - Total | 1,011,912 |
| Congregate | (579,506) |
| Home-delivered | (432,406) |

These services are basically the same as those provided under Title III.

Question: Would all of the proposed increase in funding be used only to expand the number of Tribal organization recipients, or would some of the funds be used to augment existing grantees?

Answer: Our plans are that increased funding would be used to fund up to an additional 27 Tribes.

Question: To what extent are Indians served under the Title III program?

Answer: Fiscal Year 1983 data reflect that 40,631 older Indians were provided services under the Supportive Services and Senior Centers portion of the program, 28,463 received Congregate Nutrition Services, and 7,287 received Home-delivered Nutrition Services.

## COMMUNITY SERVICE EMPLOYMENT

Question: The Department of Labor budget request is proposing to transfer a portion of funds for community service employment for older workers currently administered by State agencies from its administration to the Department of Health and Human Services (DHHS). What effect would this proposed transfer have on DHHS's ability to manage Older Americans supportive and nutrition discretionary programs?

Answer: We believe that the Administration on Aging could manage this additional responsibility effectively since our intent is not to run the program, but simply to include these funds in a single grant to the States.

Question: Will this transfer necessitate any personnel changes in DHHS?

Answer: We believe that current staff levels in the Administration on Aging are adequate to support this additional responsibility.

Question: How will this proposal enable States to do better planning or create more employment opportunities?

Answer: If this part of the program was administered by the Administration on Aging, States would no longer have to coordinate activities under the Older Americans Act with the Department of Labor. The Administration on Aging would then be the only Federal contact. The proposal would facilitate the coordination by the States of persons employed under Title V with other aspects of the Title III programs.

## SOCIAL SERVICES BLOCK GRANT

Question: Now that the Social Services Block Grant is more than two years old, have States submitted their biennial reports on how they used their funds?

Answer: To date, twelve States have submitted biennial reports. The social services block grant statute does not specify a given time for submission of these reports, such as the number of months from the close of the two year period.

Question: Have you any data yet on how many people are being served by the Social Services Block Grant, characteristics of these recipients, and types of services they are receiving?

Answer: From the pre-expenditure reports and other studies, we have general rather than specific information. The statute does not require States to report the number of people being served by the social services block grant and the Department has chosen not to require this information.

However, we do know that in general, States are continuing to provide the same types of services they provided in previous years. The most frequently offered services are protective and emergency services, child day care, and home-based services (homemaker, chore, and home management services). Protective services for children is the top priority service in almost all States. Most States make all services available to AFDC recipients and at least one home-based service available to SSI recipients.

Question: Are the provisions in the Social Services Block Grant law regarding reporting and data collection adequate for effective Federal oversight?

Answer: We believe they are. At the Federal level, we review pre-and post-expenditure reports; receive and monitor the States' audit and audit resolution process; and investigate and resolve any complaints that the State has failed to use its allotment in accordance with the terms of the Act.

As you know, the block grant legislation and regulations place great reliance for oversight and accountability on State processes. The fundamental check on the use of funds is the States' accountability to their citizens. States are required to obtain public comment on their proposed pre-expenditure report and to arrange for an independent audit.

Question: Do you have enough data to determine the effectiveness of the Social Services Block Grant, as compared with title XX of the Social Security Act prior to the block grant's inception in FY 1982?

Answer: As you know, the basic purpose of the block grants was to reduce the administrative and reporting burden on States. Therefore, we do not require detailed reporting from the States. However, we do have information from a variety of sources including State pre-expenditure reports, post-expenditure reports, audits, and major studies by GAO and the Urban Institute.

As a result we do know the States have used the flexibility under this program to provide services in areas of most pressing need. They defined their own eligibility standards and they have prioritized their service needs. In a number of cases, States have changed State administrative practices to give "mini-block grants" to sub-State areas, and where it was more practical, have centralized some State administrative practices. Overall, we believe the block grant has proven to be an effective way of providing Federal support to the States because of the flexibility that allows them to use funds in the manner most effective for them.

## HEAD START EXPANSION PROGRAM

Question: How do you justify awarding the fiscal year 1984 expansion funds using different criteria than the existing Head Start regulations set out?

Answer: The criteria upon which funding decisions would be based are consistent with current Head Start Regulations. Criteria were restated, but not changed, in order to accomplish the objectives of the fiscal year 1984 Head Start Expansion effort.

Question: Are you planning to change the regulations to reflect the criteria you used?

Answer: We are not planning to change current regulations on selection of grantees. We believe that the criteria being used in the fiscal year 1984 Head Start expansion are consistent with current regulations.

Question: Why did you not modify the new criteria as you were ordered to do by the Appropriations Committee?

Answer: The modification of the criteria was not necessary since the criteria were consistent with current Head Start Regulations.

Question: What is your current timetable for awarding the fiscal year 1984 expansion funds?

Answer: The current timetable for awarding Head Start expansion funds is the Spring and Summer of 1984 with all awards made by September 30, 1984.

Question: When will the money actually get to local Head Start programs?

Answer: Head Start expansion funds will be awarded over a period extending from mid-April until early September 1984. Notification of all applicants as to whether we will fund their applications will be made in April and May.

Question: Will they be able to spend it by the end of the fiscal year?

Answer: Local Head Start grantees operate their programs on a twelve-month funding cycle. The beginning of this cycle occurs at different times of the year for different programs and most twelve-month cycles extend across parts of two fiscal years. While all awards for expansion will be made by the end of the fiscal year, most Head Start programs will have some portion of fiscal year 1985 to actually use these funds.

Question: If not, what will happen to it?

Answer: All funds will be awarded to applicants by the end of this fiscal year.

Question: Why were the Head Start Expansion awards all made from the National Head Start office instead of the regional offices?

Answer: The Head Start Expansion awards, including negotiations with successful applicants, will be made by ACYF regional offices. Review of funding requests, the selection of panels and final ranking of funding requests were done at the national level with heavy input from the regional offices. This procedure was established to insure that criteria were applied uniformly and that panels reviewing funding requests were not from the regions where the applicants were located.

Question: Wasn't this procedure more costly and time-consuming than letting each region make the awards?

Answer: Although comparative costs have not been computed, it is possible that conducting the review at the national level was somewhat more expensive than reviews conducted in each regional office would have been. We believe that the benefits derived from a national review, especially uniformity of process and application of criteria, justify any additional costs. It is not clear that the review would have been less time consuming if it had been held at the regional offices.

Question: How much did it cost to bring the entire award process to Washington?

Answer: The cost of the review and selection process was $578,000. A substantial part of that cost would have been incurred even with a Regional Review Process.

Question: Where did these funds come from?

Answer: The $578,000 came from the $74,000,000 for Head Start Expansion. The funds were available because Head Start grantees operate on different funding cycles. Since successful applicant's program years are different, this provides savings that will be directed towards start-up costs and one-time expenditures. This phase in process will not affect our ability to fund successful applicants at an annual rate of $74,000,000.

## FOSTER CARE STATE COMPLIANCE

Question: How many States were in compliance with the foster care protections required by law in fiscal year 1984?

Answer: States may certify compliance with section 427 foster care protections requirements for fiscal year 1984 anytime until August 15, 1984. To date, 48 States and D. C. have certified compliance for fiscal year 1984. We cannot say how many States are in compliance until we complete the fiscal year 1984 reviews in 1985.

Question: How many will be in fiscal year 1985?

Answer: We estimate that all 50 States and D. C. will certify compliance for fiscal year 1985.

Question: Please describe your procedure for ascertaining whether a State is in compliance.

Answer: A two-stage review is conducted for the first year in which a State has certified Head Start compliance: The first stage of the compliance process is a thorough review of the State agency's administrative procedures, policies and practices to determine whether it has made the arrangements necessary to adequately implement the law.

The second stage involves examining a statistically valid random sample of foster care case records from throughout the State to determine whether the protections are being provided at the service delivery level.

Once a State has passed its first year review, it receives a second year review of a sample of foster care case records. Much more stringent standards are applied in this second year review.

Question: Have you carried out this procedure in all States that have certified their compliance?

Answer: Yes, we review all States to verify their compliance with these requirements.

Question: If not, when will you?

Answer: The review is conducted after the close of the fiscal year under review at a time mutually agreeable to the State and the Regional review team. We are currently reviewing States for their fiscal year 1983 eligibility.

Question: How many States have you found not to be in compliance after your investigation?

Answer: In fiscal year 1981, four States were denied eligibility and an additional five States withdrew their certifications when reviews indicated that they would be found ineligible. In fiscal year 1982 there were four denials and three withdrawals. Several decisions are still pending for fiscal year 1982.

Question: Are you collecting reimbursements of Federal funds from such States?

Answer: We have established and are implementing a procedure to deduct the section 427 funds owed by a State from future quarters' awards, when a State has been determined ineligible or has withdrawn its certification.

Question: What are you doing to help States establish their required foster care protections?

Answer: As a result of the findings of the section 427 reviews, many of the States felt the need for additional help in meeting the requirements. Regional staff have been providing considerable technical advice to States.

As each review is concluded, an exit conference is held with State officials to point out the positive aspects of their system and the areas needing improvement and to make suggestions on how to improve those areas.

## FOSTER CARE PROGRAM

Question: You indicate in the FY 1985 budget that you will be sending up legislation to provide incentives to States to keep their foster care caseloads down.

Can you give us any details of this proposal? How much money would it save the States? The Federal foster care program?

Answer: We have not made final decisions on our legislative proposal, which is still in the preliminary stages of development. The basic purpose of the proposal will be focused on working with States to create positive incentives for moving children into permanent homes. We are especially concerned about those hard-to-place children who have been in the system for a number of years, and we intend to continue the emphasis begun in the Adoption Assistance and Child Welfare Act of 1980 to assist these children.

We cannot give you exact figures on savings, since the Foster Care program is an open-ended entitlement, and States have two years to submit services claims. However, we do expect that an emphasis by States on putting children into permanent or long-term placement as quickly as possible will slow the growth of this program, and result in long-term significant savings. The budget, therefore, includes a $20 million savings.

Question: How soon will you submit legislation to provide incentives to States to keep their foster care caseloads down?

Answer: We cannot give you a specific date, but we hope to submit a legislative proposal as soon as possible, to give Congress as much time as possible to consider the proposal during this legislative session.

## COMMUNITY SERVICES AND SOCIAL SERVICES BLOCK GRANT

Question: How do you explain the fact that Congress created both these block grants under the same piece of legislation in 1981, if they were not intended to complement each other?

Answer: We believe the creation of the two blocks was largely due to the fact that many different committees were involved in the preparation of the OBRA. In the process of creating the OBRA, the House did, in fact, pass a Social Services Block Grant which included the Community Services program, as the Administration had proposed. Because of committee jurisdictions, the CSBG and the SSBG were taken up in separate conference action, resulting in the inclusion of both programs in the OBRA. This does not mean that Congress necessarily intended the two block grants to complement each other.

When the community action agencies were establish more than fifteen year ago, they were supposed to focus not on service delivery but on advocacy, institutional change and the mobilization of private sector resources. However in 1982, only 1.3% of the community action agencies' budget was leveraged from the private sector; 86.6% of the agencies' income was derived from federal funding sources and, as the public witness testimony before this committee last year made clear, "ninety cents of each dollar received by CAAs was spent in direct services to program recipients". Thus there is little difference between the kinds of activities funded under the CSBG and those funded under the SSBG. We believe that in the interest of economy, efficiency and greater flexibility for the States, Congress should pursue the idea announced in the very first sentence of the SSBG Act and merge the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant...".

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### HDS -- RESEARCH EXPENDITURES

Question: Secretary Hardy, the Post story on your research grants program quotes the director of the Institute of Gerontology at the University of Michigan as saying your administration " lets into play one very important factor: that is the political impact of what they are funding." This director went on to say that as a result his organization is now seeking funds from the National Institutes of Health because "at NIH, the predominant concern is about the quality of research. You would be naive to think there was no institutional politics at NIH. But at OHDS, thay have now got the ✓ tables turned. The likely political impact is an important aspect -- not the only aspect -- but an important aspect of their decision to make a grant." Doesn't this statement indicate that your decision not to abide by peer review panel recommendations may result in excellent research proposals being submitted to other agencies?

Answer: A fundamental philosophical tenet of this administration is that solutions to human needs are best devised by those closest to the problem, that is, communities and States. To the extent that that belief underlies the research priority areas published in our Program Announcements, policy impact is a factor. However, that does not equate with political interventions in the grantee selection process. The "political impact" of proposed projects is not a factor in funding decisions. What is a major factor, indeed the primary factor, is the field review scores. Contrary to what the press has reported, there is a very high correlation between the peer review rank and the probability of selection. The correlation is not absolute because, as in the past, the final decision rests with HDS Senior Staff who also take into account other factors such as geographic distribution and ethnic representation. All these factors are contained in the Program Announcement published in the Federal Register.

### ADOPTION ASSISTANCE PROGRAM

Question: You are requesting $12.8 million for adoption assistance in fiscal year 1985. This represents an increase of $7.8 million over your 1983 appropriation of $5 million. Last year you indicated that the average monthly number of children provided adoption assistance was expected to increase from just over 1,300 in fiscal year 1982 to 3,000 to 4,000 in fiscal year 1983. What was your final average monthly figure for fiscal year 1983?

Answer: We continue to receive claims for fiscal year 1983 expenditures which include upward revisions of children assisted. Our current estimate is about 6,300 children monthly based on actual submissions from some States and estimates from others.

Question: According to your justifications you anticipate that the average monthly number of children provided adoption assistance will be 6,000 in fiscal year 1984 and will remain at the same level in fiscal year 1985. What makes you think the program will level out at the 6,000 level after four years of vigorous growth?

Answer: Since we made the estimates contained in the justification, considerably more information, particularly from the larger States has become available concerning the number of participants in this program. We now estimate that there will be continued growth in the program in fiscal year 1985.

## FOSTER CARE PAYMENTS

Question: Last year you proposed bill language that would have capped foster care payments at $440.2 million. Mr. Iteilag explained that this cap would not reduce the amounts the States were entitled to receive in fiscal year 1984, but was intended to have a cost restraining effect in subsequent years. The Congress did not enact this "cap" language last year and you seem to have dropped it from your 1985 budget request. However, I note that you are asking us to adopt a provision that would allow the Secretary to adjust foster care payments to any State based upon foster care status. What exactly does that language mean?

Answer: We are developing a proposal to send to Congress to amend the title IV-E Foster Care Program. The proposal is still under development at this time, but its thrust will be to propose further incentives to States to effect early reunification or other permanent placement.

## SALARIES AND EXPENSES - OTHER SERVICES

Question: A look at the Human Development Services budget by object class as it appears in the Appendix to the President's budget makes it clear that obligations for "other services" will be substantially higher in fiscal years 1983 and 1984 than you initially estimated last year. The Appendix to the 1984 budget indicated that your office would spend $12.8 million and $11.2 million on "other services" in fiscal year 1983 and 1984. However this year's Appendix shows an actual expenditure of $16.6 million for "other services" in 1983 and an estimated expenditure of $17 million for the same purpose in the current fiscal year. Why were last year's estimates low by four to six million dollars?

Answer: The estimates in the 1983 column of the FY 1984 budget were based on the continuing resolution for the period October 1 through December 17, 1982 with interim levels established at the lower of the House Committee passed Labor/HHS bill for 1983, the current rate, or other specific provision of the first continuing resolution. Also, no funding for new activities or projects were authorized. When Congress later extended the funding authority under the continuing resolution through September 30, 1983, funding plans were revised based on updated annualized levels which included procurement actions for project contracts covered within Object Class 25. The actual obligation of $16.965 million in FY 1983 reflected that revision which was about $4.0 million more than previously estimated.

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## QUESTION SUBMITTED BY SENATOR QUENTIN N. BURDICK

Question: I understand your 1985 budget recommends zero funding for the ten national family resource centers funded by the Administration for Children, Youth and Families. The Region VIII Family Resource Center has gotten rave reviews from North Dakota. The Center has provided valuable technical assistance, leadership, and resource coordination to the social service people in North Dakota. They feel strongly that it has been extremely valuable. Could you please explain why the Administration is recommending zero funding for these centers next year?

Answer: The Department of Health and Human Services has funded ten Regional Resource Centers on Child Abuse and Neglect for the past eight years, for a total of $2,500,000 per year; ten Adoption Resource Centers for three years at a total of $3,500,000 per year; and ten Child Welfare Training Centers for three years for a total of $1,800,000 per year. Thus, we have provided $35,900,000 over a period of eight years for the development and ongoing support of regional resource centers in critical areas of child welfare.

In fiscal year 1982, after examining the long period of support for regional resource centers and the work which they had accomplished, and after further recognizing the limited budget resources available to the Department, we decided to consolidate the three sets of centers into one set of Regional Resource Centers for Children and Youth Services, and to provide two final years of funding before phasing out additional Federal support for the concept. In doing so we have provided an added $7,000,000 of Federal funding for the resource centers. We made this decision for two reasons: first, because we believe that after eight years the benefits from such Centers would be sufficiently known to their constituencies so as to enable their users to determine whether they wished to continue all or part of the Centers' efforts with regionally available funds; and second, because Federal financial resources are limited, and because we have spent over $42 million on this concept, we believe we should move on to other areas of need.

Because we knew this funding must draw to a close when we funded the Centers in 1982 for their final two years, we required that each Center make efforts during this period to work with public and voluntary agencies and organizations to obtain funding to continue those elements of its activities which its constituents found most valuable. We believed that States and other constituent organizations should assess the roles and responsibilities of the Centers, determine which ones were most vital, and make plans either to continue the Center's work in these areas or make arrangements for other State or regional resources to take them over.

In addition, although we did not include priorities in the fiscal year 1984 Coordinated Discretionary Funding Program specifically to provide core funding for the resource centers, each Center was free to apply for funds to carry out various priorities set forth concerning child welfare, child abuse and neglect, runaway youth and management.

Over the past ten years we have shown the vitality and usefulness of this type of resource, and demonstrated how States can work together effectively at a regional level to achieve results not attainable by individual States. We have developed a resource which regional, State and local organizations can direct and fund in the future.

## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### FOSTER CARE PROGRAM

Question: Is the block grant approach inhibiting the Federal government from ensuring its funds are not being used to turn children in the foster care program into mental health laboratory guinea pigs?

Answer: Title IV-E of the Social Security Act makes Federal funds available for foster care maintenance payments for eligible children who must be removed from their homes. Title IV-B of the Social Security Act is a closely related program which provides Federal funds for services needed by foster children and their parents. These two programs are categorical programs, not block grant programs.

To our best knowledge, children in the States' foster care system are not being used as mental health laboratory guinea pigs.

The majority of children are placed in foster care, however, as a result of abuse, neglect or other traumatic circumstances.

They are helped while in placement not only by loving foster parents but also by diagnostic and, if needed, treatment services appropriate to their age.

Such services may be provided by specially trained mental health workers, e.g., Children's Hospital special unit on child abuse, local mental health clinics, etc. Services will also be provided to the parents to reunite the family if that is possible.

Public Law 96-272, the Adoption Assistance and Child Welfare Act of 1980, emphasizes the use of preventive services to avoid the need for foster care; requires the State to provide a services program to facilitate reunification of the child with his family; and for those children who cannot return home, requires efforts to bring about a permanent plan for the child, e.g., adoption. States set their own goals and objectives under these programs based on statutory requirements and the needs of the individuals in their State. Under the Child Welfare Services programs (title IV-B) Federal funds make up less than 1/5 of total State expenditures. The balance of funding for these services comes primarily from State funds although some social services block grant funds may also be used.

If we became aware of a situation such as the one alluded to in this question, we would work with the State to see that the abuse and/or inappropriate utilization of services is corrected.

## FOSTER CARE PROGRAM

Question: Are there any regulations that protect the privacy of the child from psychiatric or psychological examination, testing, or treatment in Federally funded programs without prior written consent of the foster child's natural or adoptive parents?

Answer: There are no Federal regulations covering titles IV-B or IV-E of the Social Security Act which specifically require prior written consent from a foster child's parent or guardian before the child may receive psychiatric or psychological services. However, under most State laws there is a requirement that a minor child's parent or legal guardian must give consent in order for the child to receive medical or psychiatric treatment.

In the case of an adoptive child consent would have to come from the adoptive parents, but for a child in foster care the agency that has custody, rather than the foster parents, would have to give consent.

In relation to this question, there are two sets of Departmental regulations which have some bearing on the issue.

45 CFR Part 46A, Protection of Human Rights, covers basic Department of Health and Human Services policy for the protection of human research subjects. This part covers research conducted or funded by the Department. Research is defined as a "systematic investigation designed to develop or contribute to generalizable knowledge." Among other requirements, parents or

guardians must give their permission for children to be involved in research. Therefore, if the psychiatric or psychological services are defined as research, consent must be obtained. This provision also applies to State agencies where foster children are their wards.

45 CFR 205.50 - Safeguarding information for the financial assistance programs - places certain restrictions on the use and disclosure of information concerning applicants and recipients assisted under titles IV-E and IV-B. These safeguards apply to medical, including psychological and psychiatric, data.

Question: If not, why shouldn't there be a prohibition against such a procedure unless there is some grave reason for this examination, testing or treatment?

Answer: The specific prohibition, other than as described above, is present in State law. This negates the necessity for a Federal requirement.

Question: Has your agency received any complaints about using these children as social engineering guinea pigs?

Answer: No, we have not received any complaints.

## OFFICE OF COMMUNITY SERVICES

## STATEMENT OF HARVEY R. VIETH, DIRECTOR

## ACCOMPANIED BY JERROLD SPEERS, DEPUTY DIRECTOR

### PREPARED STATEMENT

Senator WEICKER. Dr. Vieth, do you have a statement to make?

Mr. VIETH. I have a statement. I won't read it. I'll just summarize it for you.

Senator Weicker. Go ahead.

[The statement follows:]

## STATEMENT OF HARVEY R. VIETH

Mr. Chairman, Members of the Committee, I am pleased to appear before you today to discuss the Administration's FY 1985 budget request for the Community Services Block Grant (CSBG) program. The President's budget request for FY 1985 does not include funding for the CSBG program. The request does include $3 million to cover the salaries and expenses of 40 full-time equivalent positions to close out block grant and discretionary activities of prior years.

The elimination of funding for the CSBG program need not entail any significant reduction in the range or quality of social services for the poor now being provided. Nor would the repeal of the CSBG Act necessarily signify the shrinking, much less the disappearance, of the network of some 900 community action agencies which have been receiving the bulk of the funds appropriated under the Act during the past three years.

This is because on a nationwide basis, CSBG funds account for only 12% of total community action agency funding. According to a study by the National Governors Association, funding for the community action agency network in FY 1982 from all sources was $2.7 billion. Of this amount, $315 million (12%) came from CSBG. The remainder included $36 million (1.3%) from the private sector, $13 million (.05%) from state and local governments and $2.3 billion (86.8%) from federal funding authorities other than the CSBG.

These authorities include the $1.9 billion Low Income Home Energy Assistance Program (LIHEAP) which makes extensive use of community action agencies to provide its services, the $1.1 billion Head Start Program which uses community action agencies to deliver 60 to 70% of its services at the local level, and the Department of Energy's $190 million weatherization program which conducts roughly 85% of its activities through the community action agencies. In addition, the community action agencies receive funds from a number of other federally funded programs such as the Alcohol, Drug Abuse and Mental Health Services Block Grant (ADAMHA), the Community Development Block Grant (CDBG), the Job Training Partnership Act (JTPA) and the Social Services Block Grant (SSBG).

This breakdown is for the national network as a whole, of course, and the mix will vary from state to state. In California, for example, the CSBG's contribution to the State's 47 CAA's in 1982 represented 20% of their total funding. The trend among community action agencies towards diversification of funding sources has been accelerating over the past several years, and has reached a point where the elimination of a funding source contributing an average of only 12% of a community action agency's budget does not create an insurmountable problem. In fact, many community action agencies use most of their CSBG funds for staff salaries, travel, rent, utilities and other operating costs. If the CSBG were terminated, it is not unreasonable to expect that the federal and state agencies which use the community action agencies as a vehicle for delivering their programs would collectively work out some agreement for covering the community action agencies' administrative overhead. After all, each of the programs which are supported from the various funding authorities are allotted a certain percentage for administration which they can pass on to the community action agencies.

The SSBG, whose funding is increased in the President's FY 1985 budget by $25 million bringing it to a total of $2.7 billion, is of particular relevance to the proposal to repeal the CSBG Act. The similarities between the purposes and kinds of activities conducted under the two block grants are striking. Both grants provide funds to the states for a variety of social services. For example, the SSBG funds in-home services, and protective services for adults and children. Services provided under the CSBG include all those described earlier, as well as emergency assistance to meet the needs of low-income persons in the areas of health, food, housing and employment. These services are fundamentally similar, and in each case are being offered to largely the same population.

The convergence of the two acts is equally manifest in their stated purposes. The purpose of the CSBG Act is to "ameliorate the causes of poverty in communities within the state" and each state receiving CSBG funds is required to certify, among other things, that it will use the funds to "(remove) obstacles and (solve) problems which block the achievement of self-sufficiency." This sentence echoes the underlying theme of the old Economic Opportunity Act, under which all community action programs were "to focus resources upon the goal of enabling low-income families and individuals...to become fully self-sufficient". Similarly, the stated purpose of the SSBG is not just to furnish a range of social services, but to direct these services toward five goals, the first two of which relate to self-sufficiency. They read as follows:

> "(1) achieving or maintaining economic self-support to prevent, reduce or eliminate dependency
>
> (2) achieving or maintaining self-sufficiency, including reduction or prevention of dependency

The fundamental similarity in purpose, in clientele, and in the types of activities authorized by the CSBG Act and the SSBG Act has prompted the Department of Health and Human Services to couple its request for a repeal of the CSBG Act with a proposal to amend the SSBG Act to add "alleviate poverty" to the purposes section of the Act.

One result of the enactment of the two legislative proposals would be a significant reduction in the excessive administrative costs incurred at all levels---federal, state and local---by the existence of two separate block grants in the same area of social services. Another important result would be to give the states much greater flexibility in developing the mix of services and activities best suited to the unique economic and social needs of a particular state. A recurrent theme in the various conferences and workshops on block grants conducted by the states during the past year was the confirmation of suspicions that federal priorities prescribed for categorical programs frequently differed from state and local priorities as reflected in their administration of the block grants. According to a report prepared by the National Governors Association, the experience with implementation "reinforced the thesis held by many that policy planning and prioritization of needs and services can better be performed by those closer to the target populations and service areas." The difference in prioritizing does not mean short-changing the poor. The same report goes on to say that "while there was some concern on the part of Congress and special interest groups that states would no longer target funds for those most in need, if not required under federal law and regulations, this has not proven to be the case."

The flexibility resulting from eliminating the CSBG and broadening the authority of the SSBG would also extend to the selection of local program operators, since there would be no "pass through" provision that would require the selection of a community action agency. Most governors strongly oppose the pass-through provision in the CSBG Act. But the lack of such a provision in the SSBG Act, assuming the CSBG Act were repealed, should pose no threat to the existence of the community action agencies. As I noted earlier, they would still be drawing most of their support from funding authorities other than the CSBG. Secondly, those community action agencies which have been performing well over the years need not fear competition.

In addition to block grants to the states for social services, the CSBG Act authorizes a discretionary fund which is used to support programs of national or regional significance administered directly by the Office of Community Services. These programs include the National Youth Sports Program which received $5,760,000 in 1983, and programs in the areas of economic development, rural housing and assistance to migrant and seasonal farmworkers. The total expended for these latter programs in FY 1983 was $25.5 million. Under the proposal to repeal the CSBG Act, the National Youth Sports Program would be transferred to the Public Health Service whose FY 1985 budget request includes $5,760,000 to fund this program. The Office of Community Services has also been operating two loan funds, the Community Development Credit Union Fund from which $2.7 million in loans were made in 1983, and the Rural Development Loan Fund from which $10 million in loans were made in 1983.

The discretionary programs are duplicative of other program authorities already existing within the Departments of Agriculture, Commerce, Labor, and Housing and Urban Development. It does not make sense for the Department of Health and Human Services to be funding economic development projects which are identical to projects funded from Community Development Block Grants or from Urban Development Action Grants, both administered by the Department of Housing and Urban Development. Another example of duplication is found in the program for rural housing repair and community facilities development conducted by the Office of Community Services. A very similar program is being conducted by the Farmers Home Administration in the Department of Agriculture. Finally, the Department of Labor operates multimillion dollar employment, training and housing support programs for migrant and seasonal farmworkers that are identical to those conducted by the Office of Community Services under its discretionary authority. The duplication of administrative staffs and federal monitoring and auditing created by the discretionary authority of the CSBG Act is wasteful and unnecessary. This would be true even if there were no federal deficit problem.

I am prepared to submit further documentation for the rationale for repeal of the CSBG Act outlined on this statement, a rationale which I hope this Committee and the Congress, in their concern for reducing the deficit, will find persuasive.

Mr. Chairman, this concludes my statement and I will be happy to answer any questions you or the other Committee members may have at this time.

## Biography of Harvey R. Vieth

**Position:** Director, Office of Community Services
Department of Health and Human Services

**Previous Positions:** El Paso County Commissioner
Dentist

**Military:** Lieutenant, United States Navy - 1961 to 1963

**Community Activities and Clubs:**

- Member, Colorado Springs, Chamber of Commerce
- Grand Knight, Knights of Columbus, Colorado Springs Chapter - 1966
- Kiwanis International
- Board of Directors, Family Counseling Service, Colorado Springs
- Trustee, Knights of Columbus, Colorado Springs - 1967
- Member, Colorado State Board of Health (appointed by Governor) 1968
- Board Member, Memorial Hospital - (development of New Hospital facility) - 1970
- Staff Member, St. Francis Hospital - 1970
- Member, Colorado Board of Dental Examiners, (appointed by Governor) - 1972
- President of the Audubon P.T.A. - 1974
- Senior Chamber of Commerce Liaison Committee - 1975
- Fundraiser for the Poor Children of Guadalupe, Colorado Springs

**Political Activities:**

- National Delegate to the 1972 National Republican Convention in Miami
- Member of the Credentials Committee to the National Convention
- El Paso County Republican Party, County Chairman - 1973 and 1974
- Chairman for "Reagan for President", El Paso County - 1976
- National Delegate to the 1976 National Republican Convention in Kansas City
- Elected El Paso County Commissioner - 1980

**Dental Organizations:**

- Colorado Springs Dental Society
- American Dental Association
- American Association of Dental Examiners
- Central Regional Testing Service
- Colorado Board of Dental Examiners
- PSI OMEGA Dental Fraternity
- Blue Key Honor Fraternity (standing)
- Intermountain Association for Post Graduate Dentistry - (president) - 1967
- Honorary Degree from the Colorado University Dental School - 1977
- Dental Consultant for the Springs Village Nursing Home - 1977

**Education:**

1953 : Graduated - Ripon High School; Ripon, Wisconsin
1953-1954: Marquette University; Milwaukee, Wisconsin
1954-1957: Loyola University; Chicago, Illinois
1957 : B. S. - Major: Philosophy Minor: Biology
1961 : D.D.S.

**Personal Data:** Wife: Sharon
Children: Laura, Robert, Julie, Thomas, Peter

| | FY 1984 | FY 1985 Request | Change |
|---|---|---|---|
| Low-Income Home Energy Assistance | $2,075,000,000 | $1,875,000,000 | -$200,000,000 |
| Dept. of Energy/Weatherization | 190,000,000 | 190,000,000 | --- |
| Head Start | 995,750,000 | 994,659,000 | - 1,091,000 |
| Alcohol, Drug Abuse and Mental Health | 845,178,000 | 844,955,000 | - 223,000 |
| Community Development Block Grant (HUD) | 3,468,000,000 | 3,468,000,000 | --- |
| Job Training | 3,634,898,000[1] | 3,610,624,000 | - 24,274,000 |
| Work Incentive Program | 266,532,000 | --- | - 266,532,000 |
| Social Services Block Grant | 2,675,000,000 | 2,700,000,000 | + 25,000,000 |
| Food & Shelter (FEMA) | 40,000,000 | -0- | - 40,000,000 |
| Net cuts: | | | -$507,120,000 |
| Community Services Block Grant | $ 346,540,000 | --- | - 346,540,000 |
| Overall net cuts: | | | -$853,660,000 |

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[1] Actual appropriation was $6,399,000,000 for 21 months; for comparability, 12 month funding is used for FY 1984.

BUDGET REQUEST

Mr. Vieth. The President's budget request for fiscal year 1985 does not include funding for CSBG programs. This does include $3 million to cover the salaries and expenses of 40 full-time equivalent positions to close out block grant discretionary activities.

The elimination of funding for the CSBG Program need not entail any significant reduction in the range or quality of social services for the poor now being provided. Nor would the repeal of the CSBG Act necessarily signify the shrinking much less the disappearance of the network of some 900 community action agencies which have been receiving the bulk of the funds appropriated under the act during the past 3 years.

This is because on a nationwide basis CSBG funds account for only 12 percent of the total community action agency funding. According to a study by the National Governors' Association, funding for community action agency networks in 1982 from all sources was $2.7 billion. Of this amount, 12 percent came from the CSBG, 1.3 percent from the private sector, 0.05 percent from State and local government, and 86.8 from Federal funding authorities other than the CSBG.

We are recommending a merger of the CSBG with the social services block grant [SSBG] and zero funding for the CSBG. One result of the enactment of the two legislative proposals would be a significant reduction in excess administrative costs incurred at all levels, Federal, State, and local, by the existence of two separate block grants in the same area of social services.

Another important result would be to give the States much greater flexibility in developing the mix of services and activities best suited to the economic and social needs of the particular State.

The flexibility resulting from the elimination of the CSBG and the broadening of the authority of the SSBG would extend to the selection of local program operators since there would be no passthrough provision that would require the selection of community action agencies.

Most Governors strongly opposed the passthrough provision of the CSBG Act. But the lack of such a provision in the SSBG Act, assuming the CSBG was repealed, should pose no threat to the existence of the community action agencies [CAA's].

As I noted earlier, the CAA's would still be drawing most of their support from funding authorities other than the CSBG. Second, those CAA's that have been performing well over the past years need not fear competition.

We also have a discretionary program in the CSBG. The discretionary programs are duplicates of other program authorities already existing such as Agriculture, Commerce, Labor, and HUD.

It does not make sense for the Department of Health and Human Services to be funding economic development projects which are identical to projects funded in community development block grants or urban development action grants, both administered by the Department of Housing and Urban Development.

Another example of duplication is found in the program of rural housing repair and community facilities development conducted by the Office of Community Services. A very similar program is being conducted by the Farmers Home Administration in the Department of Agriculture.

Finally, the Department of Labor operates multimillion dollar employment training and housing support programs for migrant and seasonal farm workers that are identical to those conducted by the Office of Community Services.

This duplication of administrative staffs and Federal monitoring and auditing created by the discretionary authority of the CSBG Act is wasteful and unnecessary. This would be true even if there were no Federal deficit.

During this period of soaring deficits, any nonentitlement program ought to be able to pass two tests to qualify for continued funding. First, it must show that it is not duplicative of other programs; and, second, there must be an overriding reason for continuing to fund it. The community services block grant fails to pass either of these tests.

I am prepared to submit further documentation for the rationale to repeal the CSBG Act and this concludes my statement.

Senator WEICKER. Well, let's look at the funding sources you suggest be used to offset the elimination of the community services block grant. Low-income energy assistance will be cut $200 million in fiscal 1985 under the President's budget. Job training programs are proposed to take a $290 million cut.

A slight increase in the social service block grant is more than offset by the elimination of the Emergency Food and Shelter Program. Head Start, Department of Energy weatherization, community development block grant in alcohol, drug abuse, and mental health are essentially held to current funding levels which means real cuts due to the impacts of inflation.

The net cuts to all of these come to $507,120,000 and the community services block grant, if you add that in there that's another $346 million for a total of $853,660,000; but to get to the top part of that, the $507 million, how do you expect these other programs which are being cut $500,000 to divert more resources to the community action agencies?

Mr. VIETH. Mr. Chairman, every one of those programs has a set-aside for administrative costs even if a community action agency is housing the various programs. We do not see any real savings as far as administrative costs across the board with Head Start or these other programs.

I feel even more strongly this year, that the CSBG is a layer over the other programs, and that CAA's can stand by themselves and exist by themselves. The cuts that you're talking about will not be picked up. But, on the other hand, the CSGB represents only 12 percent of the total CAA budget.

Mr. SPEERS. Mr. Chairman, if I may, I think the proposal of the administration is based on the idea that those other separate programs will stand or fall on their own appropriations and that the elimination or the zero funding of the CSBG, in and of itself, would not have that much of an effect on those other programs; the CSBG, overall, nationwide, is only about 12 percent of the funding of the community action agencies.

Senator WEICKER. Many State legislatures have recently enacted statutes for the purpose of codifying eligible services and eligible entities to be funded under CSBG. Under the administration's plan, these laws would have to be repealed, contributing to another costly and disruptive transition period for the Community Services Program.

Do you have a remedy for this?

Mr. VIETH. I feel that the increased flexibility that the States would gain would be positive and well worth the cost of the changes.

We will have language written in the SSBG that would protect community services programs by saying that we would alleviate the causes of poverty. CAA's would be protected under this change and would be able to compete for the social services block grant.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have other questions to submit to both of you for response to the record and the record will also be held open for any other questions by Senators on the committee.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### DIFFERENCES BETWEEN THE CSBG AND SSBG

Question: What is your rebuttal to last year's public witness testimony describing the differences between these block grants?

Answer: Last year's public witness testimony contended that the CSBG and SSBG were not alike in terms of (1) the populations they serve, (2) the types of services they deliver, (3) the mechanisms they use to deliver the services and (4) the intent and purposes of the two block grants. We respectfully submit that while there are some differences between the two block grants, these are minor and do not justify two entirely separate administering bureaucracies and sets of regulations at the federal level and, in many cases, at the State level.

In the first place, the populations served by the two block grants, though not identical, largely overlap. Under both grants, services are provided to low-income people. With respect to the services delivered, we are not suggesting that the SSBG pick up all or even most of the services now provided by staff paid from the CSBG. Most of these services are funded by other federal programs (Head Start, LIHEAP etc.) and need no support from the SSBG. On the other hand, the SSBG, with our proposal to enlarge its activity to include the alleviation of poverty, can be used to pay for activities now being supported exclusively from CSBG funds.

With respect to the delivery mechanisms, the SSBG is operated mainly through county welfare offices while the CSBG is operated mainly through community action agencies. But the differences are not so pronounced as to justify two separate block grants. SSBG funds can be used by county welfare offices to subcontract for services from community action agencies. As a matter of fact many county welfare offices are now using community action agencies to deliver such SSBG-funded services as child day care services, family planning services, and home management information and referral services.

Finally, differences in intent and purpose between the SSBG and CSBG are more apparent than real. As noted in the opening statement, historically the community action agencies were supposed to "focus resources on the goal of enabling low-income people to become fully self-sufficient". But two of the five goals of the SSBG also relate to the achievement of self-sufficiency by poor people. The CSBG Act speaks of ameliorating the causes of poverty while the SSBG Act seeks to prevent dependency. Dependency is a consequence of poverty. To combat one is to combat the other. To ensure that States have the authority to use SSBG funds to support any CSBG activities not already supported (as most of them are) from other federal funding authorities, the Department has proposed amending the SSBG Act to add "alleviate poverty" to the purposes section of the Act.

Question: How do you explain the fact that Congress created both these block grants under the same piece of legislation in 1981, if they were not intended to complement each other?

Answer: We believe the creation of the two blocks was largely due to the fact that many different committees were involved in the preparation of the OBRA. In the process of creating the OBRA, the House did, in fact, pass a Social Services Block Grant which included the Community Services program, as the Administration had proposed. Because of committee jurisdictions, the CSBG and the SSBG were taken up in separate conference action, resulting in the inclusion of both programs in the OBRA. This does not mean that Congress necessarily intended the two block grants to complement each other.

When the community action agencies were established more than fifteen years ago, they were supposed to focus not on service delivery but on advocacy, institutional change and the mobilization of private sector resources. However, in 1982 only 1.3% of the community action agencies' budget was leveraged from the private sector. 86.6% of the agencies' income was derived from federal funding sources and, as the public witness testimony before this committee last year made clear, "ninety cents of each dollar received by CAAs was spent in direct services to program recipients". Thus, there is little difference between the kinds of activities funded under the CSBG and those funded under the SSBG. We believe that in the interest of economy, efficiency and greater flexibility for the States, Congress should pursue the idea announced in the very first sentence of the SSBG Act and merge the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant...".

Question: If you are not really trying to abolish the nationwide network of local community action agencies, why eliminate their main source of funding for staff to carry out anti-poverty services?

Answer: The CSBG is not the main source of funding for the CAAs. The $316 million provided to the CAAs under the CSBG represents only 12% of the total budget of these agencies. 86.8% of the CAAs budget comes from other federal funding sources. As it was pointed out in the Director's opening statement, each of these other funding sources has funds available to cover administrative costs incurred in delivering services. Collectively, these allowances should be enough to offset the loss of CSBG funds. The repeal of the CSBG would not mean the disappearance of the CAAs.

## SOURCES OF FUNDING FOR COMMUNITY ACTION AGENCIES

Question: Do you really expect other programs; Low-Income Home Energy Assistance, Job Training Programs, Social Services Block Grant, Head Start, Weatherization, Community Development Block Grant and Alcohol, Drug Abuse and Mental Health, which are being cut half a billion dollars, to divert more resources to community action agencies?

Answer: Most of the activities conducted by community action agencies are funded by the programs just mentioned. Therefore, to the extent these programs are being cut, there is less not more need for CSBG funds to pay administrative costs in support of these programs. In any case, a retargetting of resources to those most in need and a more efficient allocation of administrative support from federal funding sources other than the CSBG should help offset the loss of CSBG funds. These funds represent only 12% of the total community action agency budget.

Question: Many State legislatures have recently enacted statutes for the purpose of codifying eligible services and eligible entities to be funded under CSBG. Under the Administration's plan these laws would have to be repealed, contributing to another costly and disruptive transition period for the Community Services program. Do you have a remedy for this?

Answer: All States have a process for repealing or amending State laws which are no longer necessary or appropriate to the operations of State government. There is no need for the Federal government to develop a remedy for these situations.

Question: You are not proposing any legislation this year to amend the Social Services Block Grant even though the populations to be served are defined differently---the Social Services Block Grant has no income guidelines for eligibility and the purposes of each block grant are different. If the Social Services Block Grant includes no additional funds and does not mandate community services, what incentive is there for States to fund community services?

Answer: The Department has proposed legislation to amend the Social Services Block Grant to include, as one of its purposes, the alleviation of poverty. This would permit activities formerly conducted under the CSBG Act to be conducted under the SSBG Act, at the discretion of the States. There is every incentive for the States to continue using community action agencies with proven track records to deliver such programs as Weatherization, LIHEAP, Head Start etc. Funds for these programs, which account for 86.6% of CAA expenditures, will continue to be available, along with allowances for administrative overhead.

Question: In Connecticut, the State conducts a comprehensive and participatory negotiating process to award both Community Services Block Grant and Social Services Block Grant funds. Commitments are then made for two years. It appears all SSBG funds in Connecticut are committed for FY 1985. I'm sure this must be the case in other States. What provision is there for assuring the continuance of CSBG services and grantees in these instances?

Answer: It is our understanding that no federal funds can be obligated before they are appropriated, and that any commitments made beyond a given fiscal year are always contingent on the availability of new funds. If the CSBG were not reauthorized, therefore, there would be no assurance that all activites funded by the CSBG in FY 1984 would be continued in FY 1985. But the great bulk of these activities should suffer no disruption, since the CSBG accounts, on an average, for only 12% of the community action agency budget.

Question: Without the Community Services Block Grant, there would be no specific legislation for the 34.4 million poor citizens in this country. The Social Services Block Grant may include low-income people but is not directed to them. Is there no concern about the elimination of the Federal focus and of vital services to the poor?

Answer: Vital services to the poor will continue to be provided by the whole array of multi-billion dollar programs which make up the real safety net, namely, the Food Stamp Program, the AFDC program, the CDBG program, LIHEAP, the SSBG, the Commodity Distribution program etc.

## NATIONAL ACTIVITIES UNDER CSBG

Question: What is the Administration proposing to do with the Rural Development Loan Fund, Community Development Credit Union Programs, Rural Housing and Community Facilities Development, and the Assistance for Migrants and Seasonal Farmworkers which are all authorized by the Community Services Block Grant?

Answer: Rural Development Loan Fund. The FY 1985 budget proposes no direct or guaranteed loans to be made in FY 1985 and the cash balances of the fund to be credited to miscellaneous receipts of the treasury. Existing loans would continue to be monitored. The RDLF is duplicative of programs in other Departments, most notably the rural development programs administered by the FmHA in the DoA. FmHA's rural development budget includes a $400 million direct loan program and a $300 million loan guarantee program, both of which give priority to applications from low-income communities. In addition, many economic development programs in rural areas are the recipients of loans derived from UDAG and CDBG funds administered by the Department of Housing and Urban Development.

Community Development Credit Union Program. The FY 1985 budget proposes no loans be made in FY 1985 and the cash balances of the fund be credited to the miscellaneous receipts of the treasury. Existing loans would continue to be monitored.

Rural Housing and Community Facilities Development. This is a category of the discretionary grant program funded under the CSBG. The FY 1985 budget requests a zero budget for the CSBG. This grant category is duplicative of other Departments' programs, the most notable of which is the Department of Agriculture's Farmers Home Administration.

Assistance for Migrants and Seasonal Farmworkers. This is a category of the discretionary grant program funded under the CSBG. The FY 1985 budget requests a zero budget for the CSBG. This grant category is duplicative of other Departments' programs, most notably the Department of Labor's Assistance to Migrant and Seasonal Farmworkers organizations.

Question: The Community Services Block Grant provides for direct funding to Indian Tribes upon the request of the Tribe and based on need. The Social Services Block Grant does not. What protections do you foresee for Federally recognized Tribes under the Administration's proposal?

Answer: Under a draft bill submitted by the Department to Congress, the Social Services Block Grant Act would be amended to authorize direct grants to Federally recognized Indian tribes. The bill would also authorize consolidation into a single grant, at the option of any Indian tribe eligible for more than one grant, of block grants (other than health related grants) administered by this Department.

## RURAL DEVELOPMENT LOAN FUND

Question: In conference last November on a supplemental appropriations bill, the Senate agreed to drop its amendment requiring additional obligations for the Rural Development Loan Fund, pending availability of information on the record of loans which were scheduled to be made in December, 1983. How much was obligated in the first round of Rural Development Loans last December?

Answer: In December 1983, the Office of Community Services obligated $10 million in RDLF funds to 12 recipients.

Question: What has been learned to date from this round of loans?

Answer: A number of problems have been identified by the Inspector General in examining loans made by the former Community Services Administration. OCS utilized the IG report in identifying problems and amending regulations for this latest round of loans. A more comprehensive monitoring system has been put in place.

Question: How many applications were received, and how many were funded?

Answer: The Office of Community Services received a total of 62 applications and funded 12 applicants.

Question: Could an additional $10 million be effectively used for these loans in fiscal 1985?

Answer: This program is duplicative of much larger programs to accomplish the same purposes, i.e., the rural development programs operated by the Farmers Home Administration in the Department of Agreiculture. It would be more effective to accomplish these purposes through that program.

## LOSS OF ANTI-POVERTY PROGRAMS

Question: Your budget material indicates that other programs can fund activities that would otherwise be eliminated by zeroing out the Community Services program and Work Incentive programs, which currently total $613 million. Other than the $25 million increase proposed for the Social Services Block Grant, what programs are being augmented to replace the loss of $613 million in antipoverty services?

Answer: We can answer the question only as regards the community services program operated by OCS. Other than the $25 million increase proposed for the Social Services Block Grant, we are aware of no other programs that are being augmented explicitly to replace the loss of the CSBG monies. The intent of the Department in requesting repeal of the CSBG Act is to help reduce the federal deficit through the elimination of a non-essential and duplicative discretionary program. To try to "replace" such a program would undermine this intent. As we have pointed out in the opening statement and in answers to other question put to us by the Committee, the CSBG represents only 12% of the total budget of the community action agencies. We believe there is a sufficient allowance for administrative overhead in community action agency programs supported from other federal funding sources to offset the 12% loss. The Director has also testified that other programs funded under the CSBG Act such as the rural development loan fund and the discretionary programs for for economic development, rural housing and migrant and seasonal farmworkers are duplicative of other federal programs and should not be reauthorized.

## CSBG COMPLIANCE REVIEWS

Question: Are compliance investigations being conducted under the Community Services Block Grant? How many have been ordered? In what States?

Answer: Pursuant to the requirements of the CSBG, OCS assesses ten States each year. Those States which have been assessed are as follows:

July 1982 - Minnesota
July 1982 - South Carolina
October 1982 - Maine
November 1982 - Idaho
January 1983 - Arkansas
March 1983 - Arizona
April 1983 - Tennessee
May 1983 - Wisconsin
June 1983 - Wyoming
July 1983 - Pennsylvania
August 1983 - New York
September 1983 - Missouri
December 1983 - Maryland
January 1984 - Hawaii
February 1984 - Louisiana
February 1984 - Alabama
March 1984 - Virgin Islands

Question: How are CSBG funds being used? What percent go for CAAs? What percent for Limited Purposes Agencies in the states where evaluations have been conducted?

Answer: In FY 1984, CSBG funds were used to support a wide variety of services including employment services, education services, income management services, housing services, emergency services, and nutrition services.

The legislation requires that States use not less than 90% of their CSBG allotment to make grants to "eligible entities", which are defined as "any organization which was officially designated as a community action agency or a community action program under the provisions of section 210 of the Economic Opportunity Act of 1964 for fiscal year 1981, unless such community action agency or a community action program lost its designation under section 210 of such Act as a result of a failure to comply the provisions of such Act".

We have no data as to the percentage which goes to limited purpose agencies versus community action agencies.

Question: How are the state discretionary funds being used? How much of that money goes to CAAs? What does it go for?

Answer: States are not required to report in detail how their discretionary money is allotted at the State and local level. However, States generally use discretionary funds to supplement their CSBG awards, to make specific grants of their own, or to transfer to other federally funded programs such as to Older American and Head Start programs.

Question: How are the state administrative funds used? Have the size of state staffs been increased or reduced?

Answer: Of 37 States which responded to a voluntary data collection survey, twenty-seven used the full allowable 5% for their administrative expenses. Six states were in the administrative percentage range from 3.8% to 4.8%, and four were at or between 3.2% to 2.0%. One state claimed less than 5% of the CSBG for administration in order to create one additional CAP agency in an unserved area.

States are not required to report to OCS on the number of staff working with the CSBG program. We are not able to determine if the number of State personnel associated with the CSBG program has increased or decreased.

Question: When you do compliance investigations, how do you assure that the boards of CAAs or other non-profit private organizations are properly constituted?

Answer: The assurances which each Governor signs lay out the requirements for a legally constituted board. This assurance is included in all contracts with sub-grantees. When sub-grantees apply for funding to the States, the sub-grantee is required to describe the composition of its boards.

State field representatives check this assurance during their visits to sub-grantees. During OCS' assessments, team members check records, interview field representatives, interview sub-grantee personnel and check the records of the sub-grantees.

Question: What happens to the information gathered from these compliance evaluations? What follow-up is there on the findings?

Answer: Information gathered during assessment of the States' compliance with the CSBG Act is put into a draft report which is sent to the States for comment. Comments from the States are considered and may where appropriate be incorporated into the final report. This final report is returned to the State, submitted to the Secretary of DHHS, and is generally available for public information. Any necessary follow-up is done by OCS personnel to ensure compliance with the CSBG legislation.

Question: How many states have transferred funds from CSBG to Older American Act Programs or Head Start? If you can't answer for all states, how about in those states in which you've evaluated the use of CSBG funds?

Answer: According to the FY 1984 State CSBG applications, the following six States transferred funds from CSBG to the Older Americans Act of 1965, and to the Head Start program under Sub-Chapter B of Chapter 8 of Sub-Title A of Public Law 97-35: Florida, Louisiana, Maryland, Nevada, Oklahoma and Wyoming.

Question: Have any states transferred funds into the Community Services Block Grant?

Answer: The only block grant which can transfer funds into the CSBG is the Low-Income Home Energy Assistance Program (LIHEAP). In FY 1984, the following States and amounts were transferred from LIHEAP to CSBG:

| | | |
|---|---|---|
| Illinois | - | $1,600,000 |
| Nevada | - | 360,000 |
| Vermont | - | 30,000 |
| Washington | - | 3,700,000 |
| Wisconsin | - | 251,000 |

Question: What training activities are currently being provided to states and local grantees? What percentage of the OCS budget is devoted to training activities?

Answer: OCS has given a $316,000 grant to the Center for Local and Community Research to provide assistance and support to the States in their implementation of the CSBG program. The Center provides training and assistance to the States in the developing and improving State administrative systems, particularly in the areas of planning, monitoring and evaluation of CSBG funded services and activities.

In addition, OCS provides suggestions and assistance through the evaluation of State plans and State assessments conducted pursuant to the Act. It is the responsibility of the States to determine and provide whatever assistance they feel that local grantees need in order to operate State-funded CSBG programs effectively.

Question: According to Beverly Gleason, Minnesota Chairperson of the National Association of SCSP, in a letter entered into the record last year, "In most of 1982 and 1983, grants have been awarded (by OCS to states) for only on quarter at a time and generally as much as 6 weeks after the quarter began." What is OCS' current schedule for getting money to the states?

Answer: In FY 1984, grant awards to the States were made on November 14, January 5, and April 2. We anticipate no delay in making the fourth quarter awards on July 1, 1984. The delay during the first quarter resulted from Congressional delays in appropriating funds.

OCS provides funds (awards) to the States on a quarterly basis at the direction of the Office of Management and Budget. It is OCS policy to make these quarterly awards as close to the beginning of each quarter, as possible; October 1, January 1, April 1, July 1.

## OCS STAFFING

Question: How many employees does the Office of Community Services currently have?

Answer: 64 employees are currently on board (7 are assigned to the Secretary's Task Force on Food and Shelter for the homeless).

Question: Why was the number reduced below the level of 70 that the Congress provided for in the last Continuing Resolution? Has the workload in your office been reduced since last fall when you received that information and, if so, how?

Answer: By September 1983, one of the major missions of OCS---the close-out of the former Community Services Administration (CSA) grants---had veen virtually completed. Therefore, regional staff and the close-out staff in headquarters were no longer needed. Further, OCS was funded under a Continuing Resolution enacted on October 1, 1983, which mandated that where the House and Senate differed, the lower figures would control. The House recommendation for staffing level was 55 positions. The 1984 Appropriations Bill was not enacted until late October 1983. Because of the completion of the close-out of the CSA grants, OCS underwent a major reorganization. The 55 FTE figure represents the required staff to carry out the on-going mission of the agency.

Question. How many of the employees currently on board are Schedule C's?

Answer: There are currently 8 Schedule Cs on board (two are assigned to the Secretary's Task Force on Food and Shelter for the homeless).

Question: An organization chart dated October 13, 1983, indicates that there are eight people assigned to the OCS Director's Office---all Schedule C's. What is the rationale for all those managers?

Answer: Of the Schedule C appointees serving in the Office of Community Services, three have direct managerial responsibility for the operation of the OCS programs. Others serve as advisors or special assistants for specific projects such as the Secretary's Task Force on Food and Shelter.

Question: What is the justification for the most recent downgrading of most of the civil service staff in OCS?

Answer: By September 30, 1983, one of the major missions of the OCS---the close-out of the Community Services Administration (CSA) grants---had been virtually completed. Therefore, regional staff and the close-out staff in headquarters were no longer needed. Because of the completion of the close-out of the CSA grants, OCS underwent a major reorganization, and the new OCS organization approved by the Secretary of HHS in September 1983, represents some changes in functions. As a result, new jobs were developed with new duties for this revised organization. All the positions in the reorganization were evaluated by a professional classifier who determined the appropriate levels at which those positions should be graded.

Question. How many people of the number on board were actually downgraded?

Answer. Twenty-six employees on board were changed to a lower grade---all of whom were granted retained grade and pay rights.

Question: The Deputy Director of OCS lost a major responsibility this past year---directing the operations of the Regional Offices. Was he downgraded?

Answer: The responsibility of the Deputy Director of OCS remains the same after the reorganization of the Office of Community Services as before the reorganization---that is serving as the Acting Director of OCS in the management of all aspects of the Office of Community Services. One of the major functions assigned to OCS---the closing of the grants made by the former Community Services Administration---was virtually completed by September 30, 1983. Since the regional offices and some components within the headquarters office of OCS were involved only with that function, those offices and components were no longer needed, and the Office of Community Services was reorganized. The Director and Deputy Director continue to be responsible for managing all the remaining and continuing responsibilities of the Office of Community Services.

Question: The External Affairs Specialist position used to be Director of the Office of External Affairs. With the loss of office supervision and all staff, was that position downgraded?

Answer: With the reorganization of OCS, a Schedule C appointed special assistant to the Director assumed the responsibility for external affairs as well as many other special projects as assigned by the Director.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

Question: An October 13, 1983 organization chart indicates that there are eight Schedule Cs assigned to the OCS Director's Office. Is that currently the case?

Answer: Yes.

Question: Since the Director's Office is not, to the best of my knowledge, preparing legislation, managing regional offices or performing liaison function with other Federal entities charged with representing the interests of the poor, why do you need all these high level managers?

Answer: Although the Director's Office no longer manages regional offices, the Director's Office does have a significant involvement in the legislative activity of DHHS, including the preparation of legislative proposals affecting the CSBG, the drafting of testimony for various Congressional committees and the preparation of responses to Congressional queries relating to OCS' block grant and discretionary programs. The Director's Office also continues to perform an important liaison function with other Federal agencies operating programs for the poor. A number of Schedule C appointees serve as advisors or special assistants to the Director in the areas just described, as well as for specific projects such as the Secretary's Task Force on Food and Shelter. In addition, three Schedule C appointees have direct supervisory responsibility for the management of the continuing programs with OCS.

Question: Community Action Agencies, which are funded by the Community Services Block Grant, serve as conduits for millions of dollars in federal funds for many different programs. Each of these programs set aside a certain percentage of their total funding for administrative costs. How much of this administrative money from each program goes to the Community Action Agencies for their use in administering these programs?

Answer: The States were not required to provide OCS with data that would enable us to answer the question at this time. However, staff was asked to collect the needed information on a voluntary basis and a written summary of this information will be submitted to the Committee at a later date.

## QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

### RURAL DEVELOPMENT LOAN FUND

Question: In conference last November on a supplemental appropriations bill, the Senate agreed to drop its amendment requiring additional obligations for the Rural Development Loan Fund, pending availability of information on the record of loans which were scheduled to be made in December, 1983. How much was obligated in the first round of Rural Development Loans last December?

Answer: In December 1983, the Office of Community Services obligated $10 million in RDLF funds to 12 recipients.

Question: What has been learned to date from this round of loans?

Answer: A number of problems have been identified by the Inspector General in examining loans made by the former Community Services Administration. OCS utilized the IG report in identifying problems and amending regulations for this latest round of loans. A more comprehensive monitoring system has been put in place.

Question: How many applications were received, and how many were funded?

Answer: The Office of Community Services received a total of 62 applications and funded 12 applicants.

Question: Could an additional $10 million be effectively used for these loans in Fiscal Year 1985?

Answer: This program is duplicative of a much larger program to accomplish the same purposes, i.e., Department of Housing and Urban Developments' Economic Development program. It would be more effective to accomplish these purposes through that program.

### SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until 9 a.m. on Tuesday, April 3, when it will meet again here to hear witnesses from the National Institutes of Health.

The hearing will include the Director's overview of the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Institute of Dental Research; the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute of Allergy and Infectious Diseases; and the National Institute of General Medical Sciences.

The hearing will stand in recess.

[Whereupon, at 10:27 a.m., Friday, March 30, the subcommittee was recessed, to reconvene at 9 a.m., Tuesday, April 3.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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TUESDAY, APRIL 3, 1984

U.S. Senate,
Subcommittee of the Committee on Appropriations,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, and Proxmire.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### STATEMENT OF DR. JAMES WYNGAARDEN, DIRECTOR

### OPENING STATEMENT

Senator Weicker. The hearing will come to order. Today we begin 2 days of very important hearings into the fiscal 1985 budget request for the National Institutes of Health.

NIH is the principal biomedical research agency of the Nation and is certainly the foremost institution of its kind in the world. Through the support and promotion of biomedical research, through the dissemination of research results to practicing physicians and through the training of future researchers, NIH seeks to improve the health of American people today and in the years to come.

One measure of how well NIH has performed its mission is the fact that it has supported the work of 85 Nobel Prize-winning scientists over the years.

It is important to remember that basic research is long term in nature and requires a substantial investment of time and patience and money to produce results. In NIH we have seen how the application of this principle has worked well and has served humanity.

For today, as we meet we find improved 5-year survival rates among victims of cancer, and we find there has been a substantial fall-off in the death rates from heart disease and stroke. In recent months the research community has been armed with a study spelling out exciting new research opportunities in the field of neurological disease, and on the eve of our hearings we are told by the journal Science of the isolation of a virus that may cause rheumatoid arthritis.

I could go on and on, but the point is that we are in a period of great progress and discovery and there is undoubtedly much more to come. But this has come only after the most lengthy research going back decades and generations and longer. The perseverance of dedicated scientists has brought us to a point and given us vital momentum in the war against disease. We must not let up.

And I might emphasize in that regard many of us have had family and close friends who have been touched by the tragedy of cancer. I couldn't help but note the other day my very dear friend Homer Babbage dying at 58 years of age of cancer, one of the great educational minds in this Nation. A young man who interned in my office last summer, Greg Rullman, 17 years of age, died of cancer just several days ago.

So you know as much progress as is being made, there is much more to be done. There are greater opportunities that lie ahead.

That, of course, means that we must have an NIH budget that is equal to the research opportunities before us. I regret to report that this is not the case of the budget request for fiscal 1985.

The administration proposed a budget that is only about $90 million above the fiscal 1984 level. This barely nets a 2-percent increase at a time of substantial opportunity. Moreover, the budget reduces the number of new and competing grants by about 272, and underfunds both the new and continuation grants that are provided for in the fiscal plan. In addition, research training is reduced even as the administration's own budget material recognizes that "the level of training supported today determines our research capability in the future."

Here to present this budget request is the Director of NIH, Dr. James Wyngaarden. We welcome Dr. Wyngaarden. I don't envy your task of explaining the budget, but in any event, I want you to know that I greatly appreciate the great cooperation you have given the chairman and the committee in the past year. I think you have given very solid leadership to NIH and I don't intend those comments in any way to reflect upon you.

I will let my friend Mr. Itteileg over there answer all the budget questions, all those types of questions. Actually, I have even gotten to feel very kindly toward Mr. Itteileg. [Laughter.] You do an honest job for your employer, Mr. Itteileg, and it would be very unfair in any way to criticize you. You have been very helpful in the course of these hearings.

Senator ANDREWS. You are so easy going, Mr. Chairman. [Laughter.]

Senator WEICKER. I'm just getting warmed up. Wait until 9:30 and see if you can say the same thing. At any rate, Jim, you go ahead and proceed. Incidentally, all statements today will be included in their entirety in the record and it probably is more fruitful if you could synopsize your statement and then let's just have a back and forth as to the various matters.

## HIGHLIGHTS OF BUDGET REQUEST

Dr. WYNGAARDEN. I am very happy to do that, Mr. Chairman, and thank you very much for this opportunity to defend the President's budget for fiscal 1985.

Also, before proceeding I wanted to thank you, Senator Weicker, for your visit to the NIH. As you know, Senator Hatfield was also with us during the year. We appreciate very much the special interest of the committee in the NIH.

As you have already commented, there has been very great progress in biomedical research in the past several decades. I will not take the time to cite some of the major accomplishments that are highlighted in my prepared statement, but I did want to refer very briefly to the report of the congressional Office of Technology Assessment and its recent analysis of commercial biotechnology. In its report, the OTA concluded that the United States has a commanding lead worldwide in the development and application of new biotechnology, and that more than $1 billion had been invested in 1983 to commercialize cell fusion and other related technologies that were developed with public funds in biomedical research. The bulk of these came through the NIH, either spent intramurally or in our grants mechanism, and an essential factor in that event is the training of scientists largely with NIH funds.

As you have already indicated, the momentum of discovery must be maintained and the developments of the day rest in developments of the past. In that connection I would like to cite just briefly a statement by one of the Nobelists to whom you referred, Dr. Kornberg, as follows making this forecast.

> I am confident that within 5 years the most exciting products for industry and medicine will be subjects and products no one now even talks about.

He went on to comment:

> The currently active scientists who will lead these new advances are already bored with cloning and sequencing DNA and making hybridomas. Gifted young people entering biological science will not join the cloning pack for hormones and vaccines but will devise new techniques for solving more challenging problems.

Against that brief background and the larger statements of the prepared text, let me just highlight the details of the budget. The President's budget request for NIH for fiscal 1985 is $4,566,453,000, representing an increase of $89,118,000 over the 1984 level.

This request would support 5,000 new and competing research project grants and, added to the ongoing projects, would bring the total to more than 17,000 such grants in fiscal 1985. The average cost of new and competing as well as noncompeting grants would be increased about 5 percent, and full indirect cost would be paid.

In the aggregate, most other mechanisms, such as centers, career programs, biomedical research support, contracts, and intramural research would be maintained at approximately the 1984 level. As you have already indicated, the budget would support about 9,000 research trainees including a 5-percent increase in stipends.

Provision is made for continuation of two of our major modernization projects at NIH. A total of $4.2 million is requested for repairs to the physical plant, and $6.9 million is requested for the seventh year of the program to modernize the Warren Grant Magnuson Clinical Center. The Intramural Research Laboratory Renovation Program, started last year, would be continued with funds appropriated in 1984.

And finally, the request anticipates collecting $7.5 million in fees for the cost of patient care in the clinical center not directly related to research.

In sum, the NIH request presents a budget for a realistic continuation of biomedical research and research training. The request emphasizes support for basic research and a 5-percent increase in research grant average costs. Other funding mechanisms would be supported at 1984 levels.

### PREPARED STATEMENT

I would be pleased to answer any questions that you or members of the committee might have.

Senator WEICKER. Thank you, and as I said earlier your prepared statement will be inserted in the record.

[The statement follows:]

## STATEMENT OF DR. JAMES WYNGAARDEN

I welcome this opportunity to present testimony on the President's budget request for the National Institutes of Health for Fiscal Year 1985, to report briefly on the biomedical research enterprise in general, and to discuss some of its future potential.

Before proceeding to do so, however, I wish to express my thanks to you, Mr. Chairman, and to the Members of the Subcommittee, as well as the staff, for your continuing interest in and supportive concern for the progress of biomedical research and of the NIH in particular.

Substantial investment by the Federal Government in biomedical research for nearly four decades has resulted in America's unquestioned preeminence in this vital area of science. The establishment and growth of the Nation's productive biomedical research enterprise since World War II has been one of the most remarkable developments of that dynamic period.

Evidence of the vigor of American biomedical research is apparent in every facet of that enterprise. An outstanding example was highlighted by the Congressional Office of Technology Assessment in its recently released analysis of commercial biotechnology. From its exhaustive study, the OTA concluded that the United States has a commanding lead worldwide in the development and application of the new biotechnology. The study pointed out that the private sector in this country invested more than $1 billion in 1983 to commercialize recombinant DNA, cell fusion and other related technologies that were developed with public funds directed toward biomedical research. Most of the basic research that led to these developments was conducted by or supported through NIH.

Consequently, in discussing the plans and budget proposals for the NIH, we are addressing broader concerns than the support of a Federal agency as such. Nearly 60 percent of all health-related research and development in America s universities and medical schools is funded through the NIH. Four-fifths of the NIH budget is expended through extramural awards for the support of non-Federal investigators and public and private institutions engaged in biomedical research. These researchers, together with the investigators performing research in the NIH intramural laboratories and clinics, form a substantial element of the American biomedical research community and have been responsible for significant developments leading primarily to the improvement of the health and well-being of the American people, and secondarily to the creation of totally new industries.

Dissemination of the results of NIH-funded research, both to the general public and to the biomedical community, is a key element in the improvement of the Nation's health. Computerized information retrieval systems based at NIH are used millions of times each year to provide vital information to practitioners, scientists, and educators around the United States.

The findings of an opinion survey conducted late last year by Louis Harris and Associates reflect widespread public awareness of the productivity of the Federal/academic partnership for research--and this partnership is the key element of the programs of the NIH. Sixty-eight percent of the persons surveyed approved the award of funds by the Federal Government to colleges and universities for basic science and technological research.

Any overview of the Nation's scientific enterprise should also take special note of the NIH intramural research program that continues to play a key role in the biomedical research effort. The unique expertise and facilities at NIH offer opportunities for conducting certain kinds of research that cannot be duplicated elsewhere. The intramural program's flexibility made it possible to focus the attention of experts in many disciplines on the devastating Acquired Immune Deficiency Syndrome just as the disease was being recognized in mid-1981. Although finding conclusively the cause of AIDS and the development of effective prevention and treatment measures has proved to be exceedingly difficult, there can be no doubt that the solution is nearer than it would have been in the absence of the fundamental knowledge gained in basic research on immunology over a period of years.

In the testimony to follow from each of the major NIH components, recent research accomplishments and promising developments will be presented in some detail, but I will take the liberty at this time of highlighting a few of them.

- Positron emission tomography (PET) continues to reveal more information that is helping us to understand and, in some cases, to treat a wide range of disorders. This imaging device enables scientists to observe directly the living brain as it functions. PET research conducted and supported by the NIH has already yielded new information about epilepsy, schizophrenia, and Alzheimer's disease. The medical opportunities provided by this technology have only begun to be explored.

- In mid-January, NIH announced the results of a 10-year clinical trial in 4,000 men that provided the first conclusive evidence that lowering cholesterol levels in the blood stream can reduce the rate of heart attacks. Middle aged men in the study, who were healthy except for elevated blood cholesterol, reduced their risk of death from heart attack by 24 percent and their risk of nonfatal heart attack by 19 percent by taking a cholesterol-lowering drug. Heart disease is the number one killer in this country, and an estimated 30 million Americans have elevated blood levels of cholesterol.

- Survival rates for cancer patients continue to improve. These successes are due, in large part, to research advances in radiation therapy, chemotherapy, and surgery. During the past year, an intramural scientist, Dr. Robert Gallo, has been internationally recognized for his discovery of the first virus known to be associated with a human cancer. Discovery of that virus, called HTLV or human T-cell leukemia/ lymphoma virus, has opened a realm of scientific inquiry with great implications for diagnosing and treating certain kinds of cancers. HTLV has recently been identified by NIH scientists as related to AIDS and is one of the many leads being following in the search for more information about this disease.

- Exploitation of our rapidly expanding knowledge of molecular biology is opening new vistas for improvements in prevention, diagnosis, and treatment of many diseases. Few medical tools are as versatile as hybridomas--created by the fusion of a cancer cell with a normal antibody producing cell. These hybrid cells have the unique ability to make unlimited amounts of specific antibodies--a major component of the body's "search and destroy" mechanism against cancers and viruses. I should note that although hybridomas were first produced in England nine years ago, it is fair to say that this would not have been possible without the outstanding research of an NIH intramural scientist, Dr. Michael Potter, who created the system of plasma cell tumors that are used to produce hybridomas.

- Monoclonal antibodies are now being produced in large quantities for use in NIH-supported clinical trials in patients with leukemia and lymphoma. Most scientists agree that we have only begun to realize the potential of monoclonal antibody technology in cancer, organ transplantation, and auto-immune diseases.

- Research on recombinant DNA, largely supported by the NIH, has already paid off in terms of human application. Three medical products made with recombinant DNA techniques are already being tested in clinical trials: insulin, human growth hormone, and interferon. Dr. Bernard Moss and a team of NIH scientists have used the new technique to modify Vaccinia virus--used for 200 years to produce immunity to smallpox--so that it can confer protection against influenza and hepatitis B. Work with animals suggests that the Vaccinia virus can be used for safe, effective, and inexpensive vaccines that can be stored and administered easily. These would protect against a wide range of infectious diseases.

- Recently, a private laboratory announced the isolation of the gene for the component of blood (Factor VIII) necessary for clotting. This discovery is expected to permit the production, through biotechnology, of artificial Factor VIII in the volume needed for the treatment of the Nation's 25,000 hemophiliacs and at much less than current cost. We also can expect early development of applications of monoclonal antibody and recombinant DNA techniques to modify the immune response in organ transplants, to treat female infertility and cardiovascular disease, and to diagnose defects in a wide variety of genetic diseases such as Huntington's disease.

Recently, Nobelist Arthur Kornberg made an arresting forecast on the near future of biomedical research by observing, "I am confident that within five years the most exciting prospects for medicine and industry will be subjects and products no one now even talks about." He went on to comment, "The currently active scientists who will lead these new advances are already bored with cloning and sequencing DNA and making hybridomas. Gifted young people entering biologic science will not join the "cloning pack" for hormones and vaccines, but will devise new techniques to solve more challenging problems."

Against this background of accomplishment and promise, permit me to present in the broadest outline our plans and budget for the coming year.

The President's 1985 budget request for the National Institutes of Health is $4,566,453,000 in budget authority. This represents an increase of $89,118,000 over the 1984 level.

The 1985 request would support an estimated 5,000 new and competing renewal research project grants. Added to the active continuation grants, the 1985 awards will bring the total of ongoing research project grants to 17,094. The average cost per grant of both the competing and continuing categories will be increased by approximately five percent. The 1985 proposal also provides funding for the full amount of indirect costs of research grants.

In the aggregate, the other mechanisms, such as research centers, research career programs, biomedical research support, research contracts, and intramural research will be funded at levels approximating the 1984 level.

The request for 1985 calls for funding to support approximately 9,000 research trainees, a reduction of about 9 percent from the estimated 1984 level of 9,863. The budget request includes a 5 percent increase in the stipend level for trainees.

Provision is made in the budget for continuation of two of our major modernization efforts. An amount of $4,200,000 is requested for repairs and improvements of physical plants; $6,900,000 is requested for the seventh year of the program to modernize the Warren Grant Magnuson Clinical Center. The intramural laboratory renovation program is proceeding with funds appropriated in 1984 to modify the first of the six buildings in the plan.

Finally, the 1985 request anticipates the collection of $7,500,000 in fees for the cost of patient care in the Clinical Center not directly related to research. Such costs are normally reimbursable in a non-Federal health care institution. Funds collected would be used to offset intramural clinical research expenses. The Department is examining the need for further legislation to implement this policy and is proposing appropriation language to permit the NIH to receive and use such cost recoveries.

In sum, the 1985 request for NIH represents a realistic level of Federal support for biomedical research and research training. The request emphasizes support for basic research and provides a 5 percent increase in research project grant average costs. In other funding mechanisms, the request supports ongoing programs at basically the 1984 enacted levels. Overall, the 1985 budget request reflects the Administration's commitment--even in a time of constrained resources--to a vigorous program of biomedical research and training.

Mr. Chairman, I wish to express appreciation to this Committee for its key role in making it possible for NIH to acquire the 11-acre convent property at the western edge of the NIH campus, formerly owned by the Order of Visitation. The property was transferred to the NIH November 16, 1983. After modest renovations, we will shortly be able to put the convent building to interim use for certain limited research activities and for sorely needed research conference space. In the long term, this strategically located property will be of great value for the development of NIH programs.

I am grateful for the opportunity you have given me to present this overview of the FY 1985 budget for the National Institutes of Health. More specific information will be presented in subsequent testimony by the Directors of our Bureaus, Institutes and Divisions. I hope that all of this information will be useful to you in making your difficult decisions on the allocations of public resources.

I will be pleased to answer any questions you may have.

## BIOGRAPHY OF DR. JAMES WYNGAARDEN

October 19, 1924. East Grand Rapids, Michigan

Education: Calvin College, 1942-43; Western Michigan University, 1943-44. M.D., University of Michigan Medical School, 1948.

Professional History: 1948-1951, Intern and Resident, Massachusetts General Hospital, Boston. 1952-1953, Visiting Investigator, Public Health Research Institute of the City of New York, New York. 1953-1954, Investigator, National Heart Institute, NIH; 1954-1956, National Institute of Arthritis and Metabolic Diseases, NIH. 1954-1956, Clinical Instructor in Medicine, George Washington University, Washington, D.C.. 1956-1959, Associate Professor of Medicine, Duke University Medical Center, Durham, North Carolina. 1959-1961, Associate Professor of Medicine and Biochemistry, Duke University. 1961-1965, Professor of Medicine and Associate Professor of Biochemistry, Duke University. 1963-1964, Visiting Scientist, Institut de Biologie-Physiochemique, Paris. 1965-1967, Frank Wistar Thomas Professor and Chairman, Department of Medicine, and Professor of Biochemistry, University of Pennsylvania School of Medicine, Philadelphia. 1965-1967, Physician-in-Chief, Medical Service, Hospital of the University of Pennsylvania. 1967-1982, Frederic M. Hanes Professor and Chairman, Department of Medicine, Duke University. 1967-1982, Physician-in-Chief, Medical Service, Duke University Hospital. 1981-1982, Chief of Staff, Duke University Hospital.

Professional Organizations: American Academy of Arts and Sciences, American Association for the Advancement of Science, American Board of Internal Medicine, American Clinical and Climatological Association, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association, American Society for Clinical Investigation, American Society of Biological Chemists, Association of American Physicians, Endocrine Society, Institute of Medicine, Interurban Club, National Academy of Sciences, Southern Society for Clinical Investigation, Sigma Xi.

Honors, Awards: University Scholar in Professional Schools (Medical), University of Michigan, 1946. Alpha Omega Alpha (University of Michigan), 1947. Cum laude with First Honors, University of Michigan, 1948. Dalton Scholar in Medicine, Massachusetts General Hospital, 1948. Consultant to the Durham Veterans Administration Hospital, 1956-1965 and 1967-1982. Honorary Membership in the Italian Society of Rheumatology, 1961. Consultant to the Philadelphia Veterans Administration Hospital, 1965-1967. Consultant to the Office of Science and Technology, Executive Office of the President, 1966-1972. Sesquicentennial Award, University of Michigan, 1967. Appointed to the President's Science Advisory Committee, 1972. Consultant to the Food and Drug Administration, 1972-1973. Modern Medicine Award for Distinguished Achievement, 1974. Election to the National Academy of Sciences, 1974. North Carolina Governor's Award in Science, 1974. Appointed to the President's Committee for the National Medal of Science, 1977-80. Founder's Medal, Southern Society for Clinical Investigation, 1978. The John Phillips Memorial Award, American College of Physicians, 1980. Honorary Membership in the Sociedad Medica de Santiago de Chile, 1981.

[In thousands of dollars]

| | 1983 actual | 1984 request | 1984 appropriation | 1984 revised request | 1985 estimate |
|---|---|---|---|---|---|
| Summary | $4,023.869 | $4,077,092 | $4,476,141 | [1] $4,477,335 | $4,566,453 |
| National Cancer Institute | 987,618 | 986,681 | 1,077,303 | [2] 1,077,279 | 1,101,069 |
| National Heart, Lung and Blood Institute | 624,243 | 637,738 | 703,197 | [3] 703,181 | 718,852 |
| National Institute of Dental Research | 79,290 | 80,679 | 88,163 | [4] 88,161 | 91,096 |
| National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases | 413,481 | 426,394 | 462,578 | [5] 462,567 | 475,324 |
| National Institute of Neurological and Communicative Disorders and Stroke | 297,056 | 301,554 | 335,205 | [6] 335,197 | 344,601 |
| National Institute of Allergy and Infectious Diseases | 279,122 | 289,428 | 314,117 | [7] 314,110 | 325,379 |
| National Institute of General Medical Sciences | 369,803 | 383,139 | 415,644 | [8] 415,634 | 423,853 |
| National Institute of Child Health and Human Development | 254,318 | 256,592 | 275,179 | [9] 275,173 | 280,178 |
| National Eye Institute | 141,897 | 142,333 | 154,683 | [10] 154,679 | 157,873 |
| National Institute of Environmental Health Sciences | 164,863 | 165,884 | 179,806 | [11] 179,802 | 183,755 |
| National Institute on Aging | 93,993 | 99,408 | 114,921 | [12] 114,918 | 117,390 |
| Division of Research Resources | 213,912 | 201,837 | 242,636 | [13] 242,631 | 245,728 |
| Fogarty International Center | 10,147 | 9,189 | 11,336 | [14] 11,407 | 11,426 |
| National Library of Medicine | 51,943 | 49,616 | 49,613 | [15] 50,220 | 51,320 |
| Office of the Director and Buildings and Facilities: | | | | | |
| Office of the Director | 24,683 | 26,720 | 26,720 | [16] 27,336 | 27,509 |
| Buildings and facilities | 17,500 | 19,900 | 25,040 | 25,040 | 11,100 |

[1] Includes proposed transfer of $1.294,000, from HRSA for the January 1984 pay raise and comparable transfer of $100,000 to OASH for clearinghouse management.

[2] Includes comparable transfer of $24,000 to OASH for clearinghouse management.

[3] Includes comparable transfer of $16,000 to OASH for clearinghouse management.

[4] Includes comparable transfer of $2,000 to OASH for clearinghouse management.

[5] Includes comparable transfer of $11,000 to OASH for clearinghouse management.

[6] Includes comparable transfer of $8,000 to OASH for clearinghouse management.

[7] Includes comparable transfer of $7,000 to OASH for clearinghouse management.

[8] Includes comparable transfer of $10,000 to OASH for clearinghouse management.

[9] Includes comparable transfer of $6,000 to OASH for clearinghouse management.

[10] Includes comparable transfer of $4,000 to OASH for clearinghouse management.

[11] Includes comparable transfer of $4,000 to OASH for clearinghouse management.

[12] Includes comparable transfer of $3,000 to OASH for clearinghouse management.

[13] Includes comparable transfer of $5,000 to OASH for clearinghouse management.

[14] Includes proposed transfer of $71,000 from HRSA for the January 1984 pay raise.

[15] Includes proposed transfer of $607,000 from HRSA for the January 1984 pay raise.

[16] Includes proposed transfer of $616,000 from HRSA for the January 1984 pay raise.

## BUDGET GOALS

Senator Weicker. Last November—and I intend to just skip between the various subjects and we will allow some time for Senator Proxmire and Senator Andrews to ask questions.

Last November you made a major speech to the Association of American Medical Colleges. You discussed the following as primary goals for NIH: Fund 45 to 50 percent of the approved applications for research support, increase funding $300 to $400 million per year for 3 years, increase training positions to about 10,500 over a 2-year period, spend $20 million a year for 5 years for the acquisition of sophisticated instruments, conduct a study to provide good information on the construction needs of the biomedical research community, and some other suggestions as well.

And we, frankly, think all of them are worthy of consideration. But, you have to live in the world of budgets, now, and presumably those that are established at OMB and are handed to you without necessarily further discussion. How does the budget for fiscal 1985 compare with the objectives in your talk last November? Does it set back——

Dr. Wyngaarden. Let me take those in reverse order, if I may.

The matter of research facilities is a concern to the academic community in particular. Several studies are underway with respect to research facilities that have been initiated by departments or other agencies of Government in which we have joined. We expect to issue a contract during 1984 to obtain more quantitative data in that area. From an informal context with institutions, the chief concerns are divided between animal facilities, facilities for toxic waste storage and disposal, and modernization of research laboratory facilities.

With respect to instruments, the NIH program for large shared instruments is pretty well on target. We have slightly more than $20 million in the 1985 budget in that category. The budget includes another $27 million for development of large instruments, which might be shared under a regional or even national basis. Thus the large instrument program is very much on target.

In training, the present request is somewhat below the recommended levels of the National Academy of Sciences, which are chiefly those to which I have referred. During the last 6 or 7 years, we have been at about 98 percent of the target established by the Academy Committee. The 1985 request would be about 15 percent below that recommendation.

In the area of research funding, this budget does maintain about the level of the 1984 budget or slightly lower by the figure that you have indicated, about $230 million. However, given the constraints of the economy and the deficit with which you and the administration are deeply concerned, this is a budget that will maintain the momentum of scientific discovery.

### AWARD RATE FOR RESEARCH GRANTS

Senator WEICKER. The suggestion about funding 45 to 50 percent of your approved applications is striking particularly when you consider that the fiscal 1985 budget would make awards only to about 30 percent of approved applications. Where would 45 to 50 percent take us in terms of potential scientific achievement?

Dr. WYNGAARDEN. We have a very large number of high quality applications presented each year. The historic average for the NIH has been in the 45- to 50-percent range, and many of our Institute Directors, as well as extramural advisors, suggest that this is a target that under ideal circumstances should be met or at least approached.

We did fund about 37.2 percent of approved awards in 1983. In 1984 we expect the award rate to be in the neighborhood of about 33 or 34 percent. The budget request for 1985 would fund just under 30 percent of approved awards, according to best estimates; that could, of course, vary. Thus we will not be able to fund as much as might be desirable in an affluent economic situation, but the request will allow us to fund some of the very best science submitted to NIH for approval.

Senator WEICKER. But still below historical levels?

Dr. WYNGAARDEN. Yes; that is correct.

Senator WEICKER. When you say the very best, that still must eliminate some very good, if you will, at that junction.

Dr. WYNGAARDEN. Yes; that is certainly the case. There is some very good science that we will not be able to fund this year as has been historically true through many, many years. But the situation is more stringent this year.

Senator WEICKER. Claudia points out to me that the historic average for grants, approved applications of 45 to 50 percent—last year that dropped to 37 percent. In 1985 it will drop to 33 percent.

Dr. WYNGAARDEN. In 1984 the average would drop to 33 percent; in 1985 we project that it will be just under 30 percent.

Senator WEICKER. That is setting a pattern as far as direction is concerned that I am not so sure bodes very well.

### REDUCTION IN GRANTS

One more question and we will move on to Senator Proxmire.

Your budget request provides for 5,000 new and competing grants and for a 5-percent increase in the size of grants. However the total number of new you request is 272 below fiscal 1984 and it appears that once again you may be shortchanging both new and continuation grants. Why are you reducing the total number of new grants from the fiscal 1984 level?

Dr. WYNGAARDEN. The stabilization policy of the NIH under which we have been operating for the last 4 or 5 years calls for a minimal target of 5,000 new and competing awards, and we have endeavored to meet that each of the last several years. There is some fluctuation in this system. The 1985 budget request is projected to fund 5,000 new and competing awards.

We don't really know as we proceed throughout the year whether we will be exactly at projected levels. We had the same target last year, but as the year progressed and as some funds were transferred from other categories into research grants, it was possible to fund somewhat more. Therefore, we went somewhat beyond the initial target of 5,000 grants.

Exactly where we will come out, of course, depends on the aggregate of day-to-day decisions by many study sections and perhaps a dozen different funding units.

### CURRENT SERVICES

Senator WEICKER. What would be the cost of funding the same level in fiscal 1985 as in fiscal 1984?

Dr. WYNGAARDEN. What category? This category?

Senator WEICKER. Yes.

Dr. WYNGAARDEN. The additional amount needed would be about $150 million. That is a current services estimate with respect to research project grants, new and competing. New and competing, plus noncompeting grants as well.

Senator WEICKER. And providing for 5 percent real growth in fiscal 1985, how much additional would be——

Dr. WYNGAARDEN. I am not sure I have answered your question precisely. In research project grants, an additional $150 million would be necessary to maintain the 1984 level.

Senator WEICKER. Yes; but what I am talking about is NIH overall.

Dr. WYNGAARDEN. In all research mechanisms, a total of $270 million would be needed to maintain the current services level.

Senator WEICKER. Then if we wanted to provide for 5-percent growth, again overall, what would that require? That would be—that's just current services. Now I am saying we want to increase by 5 percent.

Dr. WYNGAARDEN. In all categories? About $242 million additional would be required.

Senator WEICKER. Are you telling me that the total would be $512 over the current budget?

Dr. WYNGAARDEN. Yes; $512 million over the current budget.

Senator WEICKER. Well, I am glad—in my part of the question on this point, I think it dramatically illustrates what needs to be done. I think probably all of us in this room would admit that it is going to be very different if we had a 5-percent growth factor, but as far as I am concerned I know I certainly am going to push to keep matters at the current level.

That is $270 million more than the administration has requested.

Mr. Itteileg, do you agree with this computation as to what is required to do these various things? I am not asking you to agree on the matter.

Mr. ITTEILEG. We agree, Mr. Chairman. These numbers were discussed with the House committee as well and we have reviewed them and they are technically accurate.

Senator WEICKER. Senator Proxmire.

### RELATIONSHIP OF CHOLESTEROL TO HEART DISEASE

Senator PROXMIRE. Thank you, Mr. Chairman.

Dr. Wyngaarden, a few weeks ago a cholesterol study was released. It was discussed on the front page of the New York Times and on television. The conclusion of that study, as I recall it, was that we could sharply reduce the incidence of heart disease by reducing cholesterol in the diet. However, the study utilized a drug to reduce cholesterol levels. The people who were the subjects of the study were given the drug and a control group was given a placebo. It seemed to me that the study established that lowering cholesterol by use of the drug reduced the incidence of heart disease.

This troubles me somewhat because I felt that if we could reduce cholesterol levels through diet it would be a lot better. In fact, I understand that the Journal of American Medical Association, in its report on this study, talked about the possibility that the cholesterol lowering drug may have a cancer risk and indicated that further followup is planned for cancer specific mortality. The report said that the study supported the view that cholesterol lowering by diet would also be beneficial.

As a doctor wouldn't you initially place an emphasis on diet as a means of lowering cholesterol and only advocate treatment with a drug, which would have adverse side effects, if dietary intervention was unsuccessful?

Dr. WYNGAARDEN. I think that would be the case if it turned out that diet would be adequate for this purpose. Unfortunately, it would take very severe dietary manipulations to have any effect on the cholesterol level. There is a great deal we still don't know about the internal mechanism for regulating cholesterol synthesis, but there is some type of thermostatic control in each individual that correlates dietary intake with the rate at which the liver produces cholesterol. Frequently, reduction of cholesterol is balanced by a production of cholesterol internally, so dietary control of cholesterol is not very effective.

Of course one can do something with dietary control by reduction of foods containing large amounts of fats of certain kinds. And very severe restrictions such as the rice diet, which has been used experimentally, will reduce cholesterol somewhat but not to the effect that can be achieved with this particular drug.

Senator PROXMIRE. Of course, this committee has a tendency to get into local interests, and as you know Wisconsin is a big dairy State. [Laughter.] Wisconsin makes a lot of butter, cream, and ice cream which we enjoy eating as well as producing. From that standpoint the notion of relying on a drug would be comforting [laughter] but it goes against the grain, somehow. What is the yearly cost of this drug? Is it inexpensive?

Dr. WYNGAARDEN. Dr. Lenfant could tell us that.

Dr. LENFANT. It would cost about $150 a month. It is very expensive, indeed.

## DIETARY CONTROL OF CHOLESTEROL

Senator PROXMIRE. Why doesn't the Government sponsor a study of dietary-induced cholesterol lowering?

Dr. LENFANT. That would be a terribly expensive study to do.

Senator PROXMIRE. When you talk about terribly expensive, what are you talking about? We are talking about a disease that costs billions of dollars each year.

Dr. LENFANT. The public study would cost more than $1 billion. Some 10 years ago there was a plan drawn up to do that study which in effect was discarded because of cost. The figure of $1 billion was developed 10 years ago, so I suspect today it would be much more than that.

Senator PROXMIRE. It might cost more than $1 billion?

Dr. LENFANT. Yes.

## NUTRITION RESEARCH

Senator PROXMIRE. What proportion of the total NIH budget is devoted to dietary intervention as a means of preventing or treating disease?

Dr. WYNGAARDEN. Approximately 4.1 percent of our budget is devoted to nutrition research. In some institutes, nutrition is a very high priority, reaching as high as 8 percent.

Senator PROXMIRE. A few days ago, Dr. Wyngaarden, the Congressional Budget Office came out with an analysis of the President's fiscal year 1985 research and development budget. After speculating that an emphasis on preventative medicine research and development could slow health cost inflation, the analysis made this provocative comment. "Successful R&D might result in greater longevity and new curative techniques that actually increase health care costs by increasing the quality of service provided by the health system and the number of patients it serves." In other words if we continue to fund successful biomedical research, people would live longer and, therefore, medical care would cost more.

Dr. WYNGAARDEN. Yes.

Senator PROXMIRE. Is that correct?

Dr. WYNGAARDEN. I think it's a factual statement, but it is not an argument in my view. It is well established that the major components of our health care costs are in the elderly and what you state is correct.

## COST EFFECTIVENESS

Senator PROXMIRE. Could you tell us informally, providing details for the record, which institutes are the most cost effective, that is, which institutes to date have shown the greatest reduction in mortality and morbidity per dollar spent? [Laughter.]

I would guess that the Heart, Lung, and Blood Institute would be high on any such list.

Dr. WYNGAARDEN. Yes, it would.

Senator PROXMIRE. Can you give us that list?

Dr. WYNGAARDEN. Yes; I can. We don't have it today, but I can provide it.

[The information follows:]

## Cost Effectiveness of Research

It is very difficult to make precise comparisons between the Institutes because research performed in one Institute often has an application (and an associated cost benefit) to diseases or conditions studied in another Institute. The issue is further complicated by the difficulty in determining to what extent improvements in mortality and morbidity stem from research developments and to what extent they stem from improved lifestyle and economic factors. What I can do is give you some idea of the cost benefits of biomedical research in several disease categories.

The National Institutes of Health has long been concerned with the cost and benefits of biomedical research. In 1979, the most comprehensive analysis to that time of the cost of illness and its relationship to the role of biomedical research in reducing mortality and morbidity rates was published. 1/ The study, carried out under contract to the Division of Program Analysis of the NIH by the Public Services Laboratory (PSL) of Georgetown University, examined the economic cost of death and disease for the years 1900, 1930, 1963, and 1975.

The PSL study, after a thorough summation of the burden of illness, went on to analyses directed toward establishing the share attributable to biomedical research of reductions in work-time losses to the economy that are due to mortality and morbidity. These are not simple calculations, of course, and many factors--income levels, social stress, environmental hazards, differential accessibility of health care providers, etc.--had to be addressed. Further, assumptions were made, and tested, concerning the lag between biomedical research expenditures and the realization of benefits in terms of reduced illness and premature deaths.

The PSL study found that biomedical research advances have not affected disease categories uniformly. PSL Table 12-4 (Mushkin, p. 352), copy attached, shows health expenditures by disease category for 1930 and 1975, and the residual impact of biomedical research on the change in expenditures in terms of the percent per annum increase attributable to the residual. Changes in expenditures captured by this table could result either from a research finding that led to a reduction in the number of cases of a disease or from an improvement in the treatment technique applied to the disease. In any case, the residual includes a number of factors in addition to biomedical research.

The disease expenditure categories found positively affected by biomedical research include cancer, diseases of the circulatory system, cerebrovascular diseases, mental disorders, and endocrine and metabolic diseases. Circulatory disease and stroke tend to be concentrated in the older age groups and, with the elimination of many of the childhood diseases, have become increasingly important in terms of incidence and prevalence. Further, improvements in

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1/ Selma J. Mushkin, Biomedical Research: Costs and Benefits, Cambridge, Massachusetts: Ballinger Publishing Company, 1979.

technology that have yielded such innovations as hospital coronary care units, and breakthroughs in surgical techniques that enable the prolongation of life, have had an important effect on total costs. The same experiences are occurring with surgical techniques and treatments for cancer patients, and the improved ability to diagnose and treat diabetes and other endocrine and metabolic disorders.

In the aggregate, when analyses were carried out addressing principally the shares of reduction in death and in sickness attributable to biomedical research, the following was determined:

- The share of reduced mortality attributable to biomedical research over the 45-year period is 20 to 30 percent of the total reduction.
- The share of changes in sickness attributable to biomedical research is larger than that for deaths, when the data are corrected to exclude the effect of changes in the economic capacity to be sick and changes in perception and understanding of illnesses.

As summarized in the PSL table 14-5 (Mushkin, p. 412), copy attached, the apparent benefits from biomedical research are four to six times the cost of the research for the period 1930 to 1975.

However, as the study also found, there is no single correct way of measuring the net gains and no rule of comparison exists. Data are continually being gathered to update the analyses, and the National Center for Health Statistics (NCHS) has recently made available information concerning economic costs arrayed by medical condition and type of cost for the United States for the year 1980 (also attached). In addition, NCHS is publishing data concerning personal health care expenditures arrayed by condition, sex, and age for the United States in the year 1980. The availability of such data should permit additional analyses of the type outlined above, providing an opportunity for continued refinement of our understanding of the relationship between biomedical research and reduced mortality and morbidity in our population.

Table 12-4. Health Expenditures by Disease Category and the Impact of the Residual

| *Disease category* | *1930 health expenditures (millions)* | *1975 health expenditures (millions)* | $\frac{1975}{1930}$ | *Percent per annum increase due to the residual* |
|---|---|---|---|---|
| Infective and parasitic diseases | $340 | $2,027 | 5.96 | −.04 |
| Neoplasms | 40 | 5,279 | 131.98 | .03 |
| Endocrine, nutritional, and metablic diseases | 55 | 3,337 | 60.67 | .01 |
| Diseases of the blood and blood-forming organs | 15 | 667 | 45.07 | .003 |
| Mental disorders | 180 | 9,411 | 52.28 | .02 |
| Diseases of the nervous system and sense organs (except eye diseases) | 92 | 2,811 | 30.55 | −.01 |
| Eye diseases | 156 | 4,648 | 29.79 | .01 |
| Diseases of the circulatory system (except cerebrovascular disease) | 98 | 13,384 | 136.57 | .03 |
| Cerebrovascular disease | 18 | 2,633 | 146.28 | .03 |
| Diseases of the respiratory system | 583 | 7,571 | 12.99 | −.02 |
| Diseases of the digestive system (except dental) | 217 | 6,787 | 31.28 | −.004 |
| Diseases of the oral cavity, salivary glands, and jaws | 494 | 7,777 | 15.74 | −.003 |
| Diseases of the genitourinary system | 138 | 5,575 | 40.40 | .00 |
| Complications of pregnancy, childbirth, and the puerperium | 169 | 3,387 | 20.04 | −.01 |
| Diseases of the skin and subcutaneous tissue | 77 | 2,120 | 27.53 | −.01 |
| Diseases of the musculoskeletal system and connective tissue | 125 | 5,113 | 40.90 | .00 |
| Congenital anomalies | 11 | 432 | 39.27 | .00 |
| Certain causes of perinatal morbidity and mortality | 11 | 64 | 5.82 | −.04 |
| Symptoms and ill-defined conditions | 45 | 3,180 | 70.67 | .01 |
| Accidents, poisonings, and violence | 233 | 6,846 | 29.38 | −.006 |
| Other | 35 | 6,316 | 180.46 | .03 |

Sources: 1930 data: A. Berk and L.C. Paringer: "Costs of illness and disease, fiscal year 1930." Public Services Laboratory, Georgetown University, Washington, D.C., May 1977; 1975 data: L.C. Paringer and A. Berk: "Costs of illness and disease, fiscal year 1975." Public Services Laboratory, Georgetown University, Washington, D.C., January 1977.

**Table 14-5. Benefits from Biomedical Research and Research Costs**

| *Measure of benefits* | *Benefits less R&D costs, in billions* | *Benefits: ratio to R&D costs* |
|---|---|---|
| Value of reduced death and sickness (see Table 14-4) | | |
| 1930-75 $145-$167 | $115-$137 | 4-6 times |
| 1900-75 300-480 | 227-407 | 10-16 times |
| | *Internal rate of return* | |
| Value of year-by-year direct changes in death and sickness | | |
| 1930-75 | 46% | |
| 1900-75 | 54 | |
| Year-by-year changes in GNP attributable to reduced deaths and sickness | | |
| 1930-75 | 48 | |
| 1900-75 | 62 | |

Economic costs according to medical condition and type of cost: United States, 1980

| Medical condition | Total | Personal health care | Indirect costs | |
|---|---|---|---|---|
| | | | Morbidity losses | Mortality losses[b] |
| | Amount in millions | | | |
| All conditions | $ 426,975 | $ 219,400[a] | $70,631 | $136,944 |
| Infective and parasitic diseases | 8,431 | 4,498 | 2,547 | 1,386 |
| Neoplasms | 43,180 | 13,623 | 2,563 | 26,994 |
| Endocrine, nutritional, metabolic diseases, and immunity disorders | 12,436 | 7,656 | 2,135 | 2,645 |
| Diseases of blood and blood forming organs | 1,984 | 1,205 | 315 | 464 |
| Mental disorders | 25,554 | 20,301 | 3,682 | 1,571 |
| Diseases of the nervous system and sense organs | 22,262 | 17,499 | 2,424 | 2,339 |
| Diseases of the circulatory system | 79,438 | 33,184 | 10,532 | 35,722 |
| Diseases of the respiratory system | 39,347 | 17,305 | 16,977 | 5,065 |
| Diseases of the digestive system | 44,098 | 31,755 | 5,649 | 6,694 |
| Diseases of the genitourinary system | 16,974 | 13,162 | 2,716 | 1,096 |
| Diseases of the skin and subcutaneous tissue | 7,176 | 6,179 | 898 | 99 |
| Diseases of the musculoskeletal system and connective tissue | 22,093 | 13,645 | 8,021 | 427 |
| Congenital anomalies | 4,172 | 1,409 | 51 | 2,712 |
| Symptoms, signs, and ill-defined conditions | 10,138 | 3,968 | 2,873 | 3,297 |
| Injury and poisoning | 70,032 | 19,248 | 8,707 | 42,077 |
| Other conditions | 7,146 | 2,246 | 540 | 4,360 |
| Unallocated expenditures | 12,359 | 12,359 | --- | --- |

a. Includes expenditures that could not be distributed by medical condition.

b. Present value of lost earnings and housekeeping services discounted at six percent.

NOTE: Numbers may not add to totals due to rounding.

## MOST AND LEAST COST EFFECTIVE

Senator PROXMIRE. Can you give your judgment on which are the most cost effective, not which are the least cost effective--[Laughter.]—but which are the most?

Dr. WYNGAARDEN. I would think that the Heart Institute would be very high and the Cancer Institute would be very high. There has been enormous progress in those areas.

Senator PROXMIRE. Are you sure, because we have spent a lot of money on the work of the Cancer Institute.

Dr. WYNGAARDEN. Yes; we can document those statements very easily. Many of our other institutes deal with chronic diseases in which amelioration of suffering is perhaps much more dramatic than the life expectancy. I would think that our work with the Arthritis Institute would fall in that field. Some others deal with troublesome problems that are perhaps not so life-threatening, but I think the Allergy Institute would be in that field. We would have to be fairly precise on the end point and the benefits to which we were relating the cost.

## INDIRECT COSTS

Senator PROXMIRE. As you may know, Dr. Wyngaarden, the General Accounting Office recently came out with an indirect cost report indicating that over the last 10 years indirect costs have absorbed a greater and greater proportion of total biomedical research grants awarded by NIH. In 1972, one-fifth, or about 20 percent, of each research dollar was spent on institutional overhead. In 1982, indirect costs claimed almost one-third of each research dollar, 30 percent to be precise.

Unfortunately, the trend is continuing. It is estimated that by fiscal 1985 indirect costs will account for 31.7 percent of each extramural research dollar spent by NIH, a total of $952 million.

Can you tell us what you are currently doing to control indirect costs?

Dr. WYNGAARDEN. As you recall, Senator, last year, the NIH highlighted this problem by proposing to pay 90 percent of indirect costs; those funds were replaced by the Congress largely in response to a great deal of concern expressed by the academic institutions.

We have prepared for the Department an option paper as to how the payment of indirect costs may be addressed and reviewed. The Department has agreed with us that this should be approached, not on an agency or even departmental level, but on a Governmentwide level and has requested the Office of Science and Technology Policy in the White House to conduct such a study. The request for that study was signed by Mrs. Heckler a few months ago. It is now under consideration at the OSTP.

### DIETARY STUDY

Senator PROXMIRE. My time is up. Mr. Chairman, before I yield to you, I would like to tell Dr. Wyngaarden that it might be very useful for those who want to live longer and live healthier lives if you made that dietary study, but the study just released certainly has increased the joy of eating for many of us. I know that I have denied myself an awful lot of food that I'd love to have eaten, especially in view of that article in Time magazine.

Dr. WYNGAARDEN. There are some other potential drugs on the horizon that act by an entirely different principle. They're not ready yet for clinical testing, but they act more specifically to inhibit one of the enzymes concerned with cholesterol synthesis. I add that only to point out that, although the drug that was the subject of the trial you referred to is one approach, dietary control, which works to a small extent, might be another approach. There are other approaches coming on, so I think there is high promise in this field.

Senator PROXMIRE. I yield, Mr. Chairman.

Senator WEICKER. Senator Andrews.

### BRAN FIBER

Senator ANDREWS. Doctor, Senator Proxmire touched on something that is near and dear to my heart. It goes to a question I'd like to ask you. Sometime ago in about 1976 or 1977, we had in North Dakota, a human nutrition laboratory, it was set up under the Department of Agriculture, because we think it's idiotic that we know more about pig nutrition, for instance, than we know about people nutrition. It has since been emulated. When we put some money in to expand it, the Speaker of the House, for some reason saw what Conte and I did in the appropriations bill for North Dakota, and he felt that Massachusetts ought to have a piece of the action. So we have a human nutrition laboratory in Massachusetts and there's one under construction at Baylor. But in 1976, my wife and I were invited up there, not of course, by Harold Sanstead, the chief of the institution, because Federal employees know you don't lobby Members of Congress, but were invited by the university people to come up and take a look at this laboratory. And when we went through the whole thing, Dr. Sanstead was telling us about a fiber research, and Bill, this comes into your area, and they were using carrot fiber and celery fiber and bran fiber and a whole host of things, because that was controlled, little thin slices of bread made from the different kinds of fiber, and he said, "You know, Congressman"—that's what I was at that point in time—"we've found that our bran, not the winter wheat bran, it is the hard spring wheat bran, and when we find the hard spring wheat bran, we find a sharp lowering of the cholesterol is a hard benefit."

So we go through the dog-and-pony show, and a year or two later, the chairman and I wrote in some money. We did get expansion of the lab and that kind of thing, but on the way back to the farm, my wife who was very inquisitive, said, "Do you suppose that's a snow job or that there's something to all of that?"

And I said, "Well, I don't know." And she said, "Maybe we ought to try this hard spring wheat bran." And I said, "Well, I'll get the spring wheat bran, and I'll call the State university and get the cereal technology department to get us some, if you can find a way to cook it up in the muffins, or something like that." So we did, and she did, and we did it with Dr. Carey, and our cholesterols, neither one of ours had been very high, but we find our cholesterols lowered by about 20 to 25 percent after 6 months of eating a couple of bran muffins for breakfast four or five mornings out of the week.

And then we had a friend who worked for Blue Cross in North Dakota, and he had an extremely high cholesterol level. His got lowered 90 some odd points in about 6 months of eating bran muffins.

Now I campaigned for the Senate with a picture of my family on the front and Mary's bran muffin recipe on the back—[Laughter.]—and I got the biggest vote anybody ever did on the basis of bran muffins.

And the story was that that there are some expenditures of Government funds that are not spending but are rather investments, and the reason I bring up that story, Kellogg's came in and did an in-house story on Mary and the bran muffins, and they published a paper from the human nutrition laboratory. They also did one from the Department of Agriculture, pointing out that they found this, discovered it, nobody's ever done anything with this. Dr. Carey has a deal over there where a few of our colleagues apply to me, and if you want some sacks of hard spring wheat bran, I'll furnish it to you gratis, and you try it yourself, your cholesterol will be lowered. You can eat a lot more of that good Wisconsin ice cream and not suffer. [Laughter.]

Senator PROXMIRE. I'll be at your office this afternoon.

## INFORMATION EXCHANGE

Senator ANDREWS. Great. The point is, Doctor, the reason I bring this all up is not just to tout hard spring wheat bran but also to say what happens to these pieces of information that we come up with in the overall equation? One of the frustrating things, here we found this unique quality of a particular class of wheat bran, but a particular class, hard spring wheat brans, where do we disseminate? When does that go from the Department of Agriculture, who finds it in one of their labs, into NIH? What kind of a chain of communication do we have worked up?

See what you bring on when you're talking about ice cream?

Dr. WYNGAARDEN. First of all, Senator Andrews, I'd like to thank you publicly for the sack of wheat bran that you gave me and testify that your wife's recipe is great.

Senator ANDREWS. But did it lower your cholesterol?

Dr. WYNGAARDEN. I may not have eaten enough of it, but fortunately, mine is behaving itself anyway.

With reference to your question on information exchange, we do have several coordinating committees; in the nutrition area, there is one within the NIH and within the Department as well. This includes other branches of the Government, such as Agriculture. Once the information is published, we then have the register of the National Library of Medicine, in which virtually all the scientific literature in the world is collated and is available. One can simply ask the library for information on a given question and the relevant articles are provided as a printout. This is, of course, very widely used throughout the United States, and as a matter of fact throughout the world, as a reference for medical libraries, academic health centers, and university research centers.

Senator ANDREWS. Is anyone—following up on my conversation with Bill on this bran? Has your shop taken a look on the initial findings in this Department of Agriculture laboratory to see if they are substantiated by the research that you have done in-house at NIH or any other place?

Dr. WYNGAARDEN. I don't know that we have, but we should do that.

Senator ANDREWS. I'd be interested in any information derived for the record from that.

### RELEASE OF NEW DRUGS

One other review question, before I get into the dollars and cents funding. We passed an orphan drug bill about 1 year ago and brought, of course, to mind to all of us, the fact that some drugs are simply not available here yet. Many drugs we don't want to put on the American market, because we're not absolutely sure of side effects and harmful, of course, impact on individuals using them. Where do we have the happy medium? Do you feel that there are drugs available to, shall we say, your PM patients that should be available on the American market? Is food and drug moving at an appropriate speed in registering and making available these drugs or are they being overly cautious or conversely not cautious enough, in the opinion of your shop?

Dr. WYNGAARDEN. We are tangentially involved in the Orphan Drug Program, and we meet regularly with the members of the FDA on this and other matters. In general, my opinion would be that the FDA does an excellent and highly responsible job of regulating the release of drugs for use in the American market. There are some minor disparities, both ways. Drugs might be released here first, and drugs might be released in Europe first. My own knowledge of this is not such that I would want to be critical of the system as it presently operates.

Senator ANDREWS. But you think it's moving at about the appropriate speed?

Dr. WYNGAARDEN. I would think so.

### CHRONOLOGY OF BUDGET REQUEST

Senator ANDREWS. Doctor, to get down to the budget, which is why we're here today. You point out that your increase in general funding for NIH for 1985 is only 2 percent. What did you ask for?

Dr. WYNGAARDEN. The NIH estimate to the Public Health Service was $5.173 billion. The Public Health Service estimate to the Department was $4.232 billion. The Department estimate to OMB was $4.318

billion. Those figures were all based on the President's request for 1984. At that stage the OMB decided to base the President's 1985 request on congressional action for 1984. Thus, the President's budget for 1985 is actually higher than the Department estimate to OMB.

Senator ANDREWS. The President's budget is what?

Dr. WYNGAARDEN. $4.566 billion.

Senator ANDREWS. Now what were your requests, in percent, over that? It's about—you asked for about a 12-percent increase, didn't you, and you got about 2? Or is my arithmetic that accurate?

Mr. ITTEILAG. The difficulty in answering that question, Senator, is not related to the accuracy of your arithmetic. I think it is accurate, but the fact that, as Dr. Wyngaarden was saying, the base upon which the initial estimates were done, changed any course of major development. In other words, between the time that Dr. Wyngaarden submitted a budget to the Assistant Secretary for Health, at the time that decisions were made on the President's budget, the Congress took action on fiscal year 1984 appropriations and added about $400 million to the 1984 President's budget.

Senator ANDREWS. That's true, except for the fact that Dr. Wyngaarden, on the basis of the information he got from his various research team leaders, asked for $5.172 billion. He got, finally, after all the flesh-outs and the change orders, and what not, $4.5 billion. In other words, he asked for, I would assume—actually, he asked for more than you asked for, about a 14-percent increase, and you got a 2-percent increase.

Mr. ITTEILAG. That's correct. That's correct. An additional point being made, though, and I say this only on a technical basis, is that had Dr. Wyngaarden known that the 1984 budget was, in fact, going to turn out $400 million higher than the President had requested, his request of $5.2 billion might have been adjusted upward on that basis alone.

Senator ANDREWS. So you're saying his request of $5.2 billion would have been adjusted even further up?

Mr. ITTEILAG. I say that only so that we can——

Senator ANDREWS. You're making the picture worse. [Laughter.]

You're supposed to be the hard-nosed, steely-eyed—you're not supposed to be on the side of the people on the research program.

Mr. ITTEILAG. Senator Andrews, the point is that I don't want to deal in misconceptions here, and if I didn't say that, Claudia Ingram would tell you that subsequently. So I think it's important that we present accurate information.

Senator ANDREWS. Well, the reason I went into that was to get all the information and the data out on the table.

Doctor, I would assume then that you don't feel you can continue to support good quality research at an adequate pace with a 2-percent increase that you finally ended up with, compared to the 12 to 14 percent you asked for. Isn't that appropriate and correct?

Dr. WYNGAARDEN. The pace will be somewhat slower; yes.

### RENOVATION PROJECTS AT NIH

Senator ANDREWS. Could you briefly describe the current status of the two major renovation efforts you have under way at NIH and what funds are included in this budget?

Dr. WYNGAARDEN. Yes; we have included $4.2 million for repairs and improvements in the physical plant and $6.9 million is requested for the seventh year of the 10-year program to modernize the Warren Grant Magnuson Clinical Center. We have an intramural laboratory round-robin renovation program for which no funds are requested in the 1985 budget. That program will go ahead with funds appropriated in 1984, but at a somewhat slower pace than would otherwise be the case. We are in the initial stages of our plan to renovate six laboratory buildings that were constructed in the 1930's for the most part.

Senator ANDREWS. Can you provide any further information for the record?

Dr. WYNGAARDEN. Yes.

[The information follows:]

## RENOVATION PROJECTS AT NIH

### CLINICAL CENTER MODERNIZATION

Since the original planning and construction of the clinical center over 30 years ago, we have made great advances in American medicine. Yet, over these years, the center has undergone only modest alterations, generally to satisfy unique program developments or equipment requirements. Extensive alterations at the clinical center are now necessary to upgrade patient care and medical support spaces to remove functional obsolescence and repair physical deterioration; to satisfy the latest code requirements for the handicapped, for environmental health, and for the safety of the patients and the staff; and to integrate the activities in the clinical center with their functional counterparts in the new ambulatory care research facility [ACRF] completed in fiscal year 1982.

We anticipate that the clinical center modernization will involve approximately 50 discrete projects spanning a 10-year period, at a total estimated cost of $62 million (based on 1985 dollars).

Adequate lead time and careful phasing of these projects must be ensured in order to minimize the impact on patients and research endeavors, as well as to synchronize individual projects with the ACRF schedule. Alteration projects appropriated or authorized for funding through fiscal year 1984 total $31.4 million. The 1985 request of $6,900,000 would fund the activities in the seventh year of the project; these include renovation of patient care units to accommodate modern procedures and equipment and to correct obsolescence in nursing stations, medical support systems, and utilities.

### LABORATORY RENOVATIONS

Laboratory buildings 2, 3, 4, 5, 7, and 8 represent about 20 percent of the total laboratory space on the NIH campus and constitute 30 percent of the laboratory space outside the clinical center and ACRF. These buildings have been operational for approximately 40 years, and although they are structurally sound, their support systems and interior architectural features are obsolete and dangerously deteriorated.

The plan calls for a round robin of renovations and occupancy, culminating with the demolition of building 9, which has been determined unsuitable for rehabilitation. Building 8 was chosen for the initial step in the renovation process as it can most easily be vacated (as it is relatively small), yet is physically situated so that it can be expanded to accommodate personnel from a larger building in the subsequent phase of the renovations.

Even though there are no funds for the laboratory project in the 1985 request, the renovation of building 8 and the design of building 4 will continue in 1985. Renovations are planned for the other buildings over the next 9 years.

### CLINICAL CENTER REIMBURSEMENTS

Senator ANDREWS. The 1985 budget states that $7.5 million is anticipated from third-party reimbursements for services at the Warren G. Magnuson Clinical Center.

What is the status of this proposal, and is legislation required?

Dr. WYNGAARDEN. The 1985 budget assumes the collection of $7.5 million related to clinical services rendered to patients in the clinical center that might be judged not to be a part of the research activity itself. At present, the Department is preparing proposed legislative language that would permit NIH to use and receive such cost recovery measures.

Mr. Itteilag may want to speak further to that. It's our opinion that new legislation would be required.

Mr. ITTEILAG. We would agree with that, Senator, in terms of having the money used by NIH that would not require action except by the Appropriations Committee. So in terms of the whole concept, we've pretty much concluded that it's complicated enough to require legislative action by the Congress. We were not certain of that when the budget was submitted.

Senator ANDREWS. If you don't get this legislative action, then will you need additional funds to make up for the unrealized reimbursements?

Mr. ITTEILAG. I would think it would be fair to say that is a true statement.

### FTE REDUCTION

Senator ANDREWS. Your budget request reflects a reduction of 588 full-time equivalents for 1985 over the 1984 level of 13,595. What's going to be the impact, Doctor, of such a large reduction in staffing? Are you going to end up firing the young scientists who have extensive training and who would be the most vulnerable and who are also the most needed in the continuation of this work that has been going on at NIH?

Dr. WYNGAARDEN. We would attempt to absorb that reduction with the smallest impact on research activities that we could arrange. It's still a very tentative plan, but at present, we would plan to reduce the Intramural Research Program by 235 full-time equivalents, research management and support by 146, and central services by 207. The Intramural Research Program might include some of the category that you indicate. We're not sure that we could achieve this reduction without, for example, reducing our Summer Employment Program or perhaps the young scientists who come to NIH for research training, but we would make every effort to avoid that, if possible.

### AVERAGE COST INCREASE

Senator ANDREWS. Your budget provides for a 5-percent increase in the average cost of research project grants. Is this sufficient to pay full cost?

Dr. WYNGAARDEN. No; it would require an average reduction of 6 percent of the new and competing awards and 5 percent in the noncompeting continuation awards.

Senator ANDREWS. In other words, you're going to need a 12- to 18-percent increase to be adequate to cover full costs?

Dr. WYNGAARDEN. No; if we were to pay full costs with no reduction whatsoever, an increase of 5.9 percent, or $146 million, would be required.

### RESEARCH TRAINING

Senator ANDREWS. Now for fiscal 1985, 9,000 research trainees are to be funded. This is a reduction of 9 percent over fiscal 1984, when you had 9,863 funded. Since 1978, my people tell me there have been an average of 10,600 trainees per year funded.

Now what impact is this 9-percent decrease, 9-percent reduction from the norm that you've carried on over the last 5 years have on medical research and medical care 5 years from now, even a decade from now?

Dr. WYNGAARDEN. About half the total trainees that we support are undergraduates, chiefly students working toward Ph.D. degrees. Of the postdoctoral trainees, about half are M.D.'s. Therefore, the reduction would be felt at several levels. It is, however, a reduction that I think could be sustained for a year or two. There is no question that it would have some impact on the availability of scientists some 5, 10, or 15 years from now.

Senator ANDREWS. In other words, what we're doing is, we're "eating up our seed corn," as they say on the farm?

Dr. WYNGAARDEN. That would be, I think, an apt North Dakota statement

Senator ANDREWS. Finally, how many research trainees are U.S. citizens, and what are the numbers that represent foreign countries? What percent do you have of foreign countries?

Dr. WYNGAARDEN. We have about 1,000 noncitizens in training at the NIH. At some point during the course of the year, there might be 1,500.

Senator ANDREWS. That's been relatively stable over the last few years, in order to bring contacts from overseas here and continue the exchange?

Dr. WYNGAARDEN. Yes; these scientists frequently become leading scientists in their home countries. They also go back as friends of the United States.

Senator ANDREWS. So we're not doing any more as a benefit to their country than it is a benefit to our country?

Dr. WYNGAARDEN. It's mutually beneficial. They do very important research while they are with us.

Senator ANDREWS. Thank you very much, Doctor. Thank you, Mr. Chairman.

Senator WEICKER. Thank you. I want to know if anybody out there has a recipe for blueberry muffins that lowers your cholesterol? [Laughter.]

I hate bran muffins! [Laughter.]

Senator ANDREWS. You haven't tried Mary's. We'll provide the bran free. There's one other thing, Doctor. You've got to use some sunflower oil in making the muffins, because sunflower oil has the highest percentage of unsaturated fat. If you could only get the labeling laws changed, we'd sell a lot more sunflower oil.

Just stick with me and you'll be in good shape. [Laughter.]

### NURSES IN RESEARCH

Senator WEICKER. Senator Inouye has the following question: The committee has been concerned that our Nation's schools of nursing have not received sufficient attention from NIH.

For example, we understand that less than $1.5 million went to schools of nursing and only 0.6 percent of public advisory members are nurses.

What has NIH done to address this issue?

Dr. WYNGAARDEN. We have looked very carefully at the success of applications accepted from nursing schools. We are not always sure whether the applications are from nurses or from other scientists in nursing schools.

The success rate of these applications at the NIH in the last few years has been approximately the same as those of the universe of applications; about a 30-percent funding rate. We don't receive a large number of such applications, which is a reflection of the fact that the mission of the NIH is fundamentally that of doing biomedical research.

The research conducted in nursing schools contains some that is central to the overall mission of the NIH, but a great deal of the research conducted in nursing schools is in the area of health services research that has to do with nursing arts and nursing practices. This is very important in our view, but the overlap with NIH research is somewhat smaller.

We do have some important areas in which nursing-related research is absolutely central; several of our institutes have programs of that kind, such as the Cancer Institute and the Heart Institute. The Aging Institute and Child Health Institute also have a fair amount.

One of the emphases that Dr. Franklin Williams, the new Director of the Institute on Aging, will testify to later is concerned with joint projects in which nursing participation is absolutely central.

There is, for example, the teaching nursing home concept, which was started by Dr. Butler a few years ago in the Aging Institute. There is a project on the control of incontinence in the elderly, which involves nurses as part of the project. Therefore, we have such areas, but they're not numerically large.

I have recently appointed a committee at the NIH to review the participation of nurses in research programs at the NIH. This is being chaired by Dr. Williams and should report in 5 or 6 months on their discoveries.

We want to send the message to the nursing community that we're very much interested in their participation in the projects of the NIH where they can do so without radical change in focus of the research of the NIH.

We are also addressing the participation of nurses on our advisory committees. Just in the normal rotation, we have lost a few and will try to replace those.

I would point out, however, that, in general, appointment to NIH advisory committees is not based on representation of specific constituencies so much as on bringing particular research and advisory skills to the NIH. If we need people in pharmacology, we search for them in pharmacology irrespective of the degree that that individual might hold. Nevertheless, we will try to increase the number of nurses participating in our advisory committees during the next year or two.

### CLINICAL TRIALS

Senator WEICKER. The subcommittee notes that in fiscal 1984 you provided funding for about 19 new clinical trials covering such major areas as age, cancer, and stroke. What are your plans for clinical trials in fiscal 1985 and how do these compare in amount and quality with the present fiscal year?

Dr. WYNGAARDEN. The 1984 estimate that we have includes 26 major new clinical trials at a cost of about $20 million. The total amount of funding for all clinical trials in 1984 is estimated at $220 million. The 1985 estimate for all clinical trials is $225 million.

We have only two new clinical trials currently in the 1985 budget. One of those is in the Heart Institute and deals with agents that affect left ventricular function in heart failure. The other is in the NIADDK and deals with the trial of an agent that affects the cutataxin in a disease called porphyria.

### ACQUIRED IMMUNE DEFICIENCY SYNDROME [AIDS]

Senator WEICKER. One last question before I start moving with respect to the institutes.

Just where do we sit on this matter of AIDS right now?

Dr. WYNGAARDEN. We have a great deal of work going on in AIDS. The total estimate of expenditures in 1984 is in the range of $47 million in the Department. In 1985, it is about $54 million in the Department; of that, $40 million would be at the NIH.

We, therefore, have a very substantial effort. There are some interesting recent developments that are likely to be announced within a few weeks or months that are nearing completion. Considerable progress has been made in understanding the condition and in defining the agents that produce the range of infections that these patients are subject to, and even making headway on a possible causative organism.

Senator WEICKER. You feel these are matters that would be announced within this year, calendar year?

Dr. WYNGAARDEN. I would think so.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Well, I thank you very much. I have other questions, as do other members of the committee, for response to the record and I look forward to working with you in the future.

Dr. WYNGAARDEN. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET REQUEST

Question: Your budget request provides for 5,000 new and competing grants and for a 5% increase in the size of grants. However, the total number of new grants you request is 272 below fiscal 1984 and it appears you once again may be short-changing both new and continuation grants. What impact will your request have on maintaining the momentum of biomedical research--and why don't you go for real growth rather than falling back?

Answer: We believe that supporting 5,000 new and competing grants will ensure a stable and predictable level of research support and contribute substantially to a strong knowledge base in the biomedical sciences. Although investigator-initiated research is our highest priority, our budget request also seeks to meet the resource requirements of other priority research activities.

Question: You project the average cost of new grants at about $144,100 in fiscal 1985. To what extent does this fall short of study section recommendations for the average cost of new grants?

Answer: The average cost of a new and competing research project grant at study section recommended levels is projected to be $153,300 in 1985. This represents a reduction of approximately 6 percent.

Question: You project the average cost of noncompeting continuation grants at about $145,100 in fiscal 1985. How far below the full commitment level is this amount?

Answer: We estimate that the full commitment level for a noncompeting research project grant will be $153,400 in 1985. This represents a reduction of approximately 5 percent.

### TRAINING CUT

Question: Your justification presents a very clear picture of the importance of training new biomedical researchers. You recognize that it "takes years to nurture and develop outstanding investigators and that the level of training supported today determines our research capability in the future." You are stealing my lines. Why in the face of such eloquence do you propose to reduce training slots from 9,863 in 1984 to 9,000 in the coming fiscal year?

Answer: Some very difficult decisions had to be made in allocating available funds among many competing demands. Our highest priority remains the support of investigator-initiated research project grants. Within the context of this budget, we believe the support for 9,000 trainees is appropriate. I might also note that each trainee will receive a 5-percent stipend increase under our request.

Question: How does your proposal for training compare to the level of NIH training recommended by the National Academy of Sciences --and how does it compare with the yearly average since 1978?

Answer: The National Academy of Sciences (NAS) in their most recent report on Personnel Needs and Training for Biomedical and Behavioral Research recommends that 12,495 research training positions be supported in 1985. The NIH estimates its share of this number to be 10,500. The 1985 request will support approximately 86 percent of the NIH portion of the NAS recommendation. The numbers of full-time training positions since 1978 are as follows:

| Fiscal Year | Full-Time Training Positions |
|---|---|
| 1978 | 11,123 |
| 1979 | 11,197 |
| 1980 | 10,664 |
| 1981 | 10,695 |
| 1982 | 10,406 |
| 1983 | 10,570 |
| 1984 est. | 9,863 |
| 1985 est. | 9,000 |

## FEE SYSTEM AT CLINICAL CENTER

Question: I've seen a lot of ideas for cutting the budget, but now comes your proposal to start charging user fees to patients at the NIH Clinical Center. You say you will seek fees for "nonresearch services" provided to patients at the Clinical Center? What are "nonresearch services" and do you propose to get these fees by squeezing victims of cancer and heart disease, or by going after their health insurance? Suppose they don't have health insurance?

Answer: Although the NIH Clinical Center serves solely as a research hospital in which knowledge can be gained regarding human health and disease, many patients participating in research protocols receive treatment that would be required regardless of whether the patient was participating in a research study. Since the patient would need these additional services anyway, the proposal to bill patients is consistent with the overall administration policy regarding user charges for such services.

Question: Wouldn't this idea require legislative changes--and what have the legislative committees told you about your proposal?

Answer: Legal authority does exist to bill patients for such user fees under 21 U.S.C. 9701, the so-called User Fee Statute, which was part ot the Independent Office Appropriation Act of 1952. The Department is currently studying the need for additional legislation which would enable the NIH to collect reimbursements from third party payors. The approach being considered includes the following elements:

- o Amending the NIH authorizing statute to create a legal obligation on behalf of patients to pay for non-research aspects of their treatment at the Clinical Center.
- o Including in the Appropriation language for the Office of the Director authority for NIH to collect and use fees for the purpose of supporting Clinical Center operation.
- o Amending Title XVIII of the Social Security Act (Medicare) to remove the bar on payment to Federal hospitals as it relates to the Clinical Center.

- o Overriding private insurance contract prohibitions of payment for service provided by Federally owned hospitals.

Question: Is this another idea floated by OMB, or was it originated by NIH? What is your professional view of the proposal?

Answer: The idea for the patient fee system proposed in the President's 1985 request was originated within the Public Health Service. Although, in general I support the proposal, I do have several concerns regarding patient recruitment, a need for legislation, and the eventual residual monetary gain to the government.

## CLINICAL TRIALS

Question: What clinical trials are needed and ready to be undertaken, but will not be conducted because of the limitations of your budget?

Answer: The Institutes have identified 40 major new clinical trials, which will be ready for initiation in 1985, but will have to be postponed because of budgetary constraint. The following listing groups these trials by Institute; they have been prioritized within each Institute:

### NCI

Intergroup clinical trials within the clinical cooperative group program - A number of intergroup clinical trials are now ready for investigation. Among the most promising are:

a) Wilm's Tumor - Studies are needed to develop less aggressive curative treatments with less morbidity for children with this disease.

b) "Uncommon" Tumor Studies - A comprehensive approach is needed for patients with relatively uncommon but treatable cancers. Only by linking medical specialists from different disciplines can this scientifically important group of diseases be addressed.

c) Head and Neck - A joint effort between the cooperative groups and the cancer centers is desired to investigate new combinations of radiotherapy, surgery, and chemotherapy to cure a greater number of patients with less disfiguring surgery.

d) Testicular Adjuvant Chemotherapy - Adjuvant chemotherapy now prevents 50% recurrence in patients with high risk stage II disease. An additional study is desired to investigate whether adjuvant chemotherapy after removal of one or both testes may cure without the morbidity of retroperitoneal node dissection.

e) Melanoma - To determine whether more limited surgery with or without regional node dissection will cure patients with intermediate thickness melonoma. This study has major significance in determining whether morbidity and hospitalization can be reduced.

f) Limb Perfusion of Melanoma Patients - Regional limb perfusion of chemotherapy is a promising therapy for patients with locally advanced or incurable melonoma. It can eliminate local tumor and is preferable to amputation. A cooperative effort of those surgeons skilled in this technique is needed to define the benefits of this therapy and to identify which patients are likely to be helped by this approach.

g) Specific Adjuvant Immunotherapy in High Risk Colon Cancer - in spite of promising leads, there has been little recent progress in improving prognosis in patients with poor-risk completely resected colon cancer. Specific immunotherapy given after surgery when there is a minimal tumor burden is an important new area of research in this disease which should be pursued.

Clinical Cooperative Groups - This initiative will upgrade the skills of community physicians and allow the accrual of additional patients into NCI sponsored clinical trial programs. The additional data obtained through community hospital/physician participation will allow earlier conclusions to be drawn regarding trial protocols.

Phase I/II evaluation of additional biological response modifiers - The recent advances in genetic engineering and other areas of science has now made available new and highly purified biological response modifiers. Clinical evaluation of these agents for both safety and efficacy are needed.

Therapeutic trials with conjugated monoclonal antibodies - Monoclonal antibodies can specifically target to individual tumors and in so doing can deliver cytotoxic agents with little or no side effects and toxicity and with a high therapeutic index.

Treatment of HTLV associated cancer - Human T-cell leukemia/lymphoma virus (HTLV) has been identified as a causative agent in acute T-cell leukemia (ATL) and possibly other cancers. The virus is endemic in the Caribbean.

Clinical evaluation of radiation modifiers and innovative radiotherapy techniques - This is a coordinated effort to stimulate the clinical investigation of each radiation modality (hyperthermia, radiosensitizers, radioprotectors, radiolabelled antibodies, charged particle radiotherapy, brachytherapy, intraoperative radiotherapy, etc.) or combinations thereof to establish more rapidly their value in the treatment of cancer and hasten their integration into multimodality treatment regimens.

## NHLBI

Hypertension primary prevention trial - Individuals predisposed to the development of hypertension will be tested for feasibility and efficacy of nutritional intervention. Specifically, weight reduction diets and/or reduction of sodium intake, with or without increased potassium intake, will be evaluated to determine effectiveness in preventing the elevation of blood pressure (Phase I), and consequently the incidence of hypertension (Phase II).

Percutaneous transluminal coronary angioplasty - Percutaneous transluminal coronary angioplasty (PTCA) is a relatively new technique that permits dilation of a narrowed coronary artery by placing a balloon catheter in the narrowed coronary artery and inflating the balloon. An experienced cardiologist can perform angioplasty with mortality risk of less than 1% and relieve angina for as many as 80% of coronary patients. This procedure is far less invasive than coronary artery bypass surgery and may replace bypass surgery in some patients. A clinical trial is designed to permit a direct comparison of the PTCA method and that of bypass surgery in patients with severe angina.

NIDR

Clinical studies of chemotherapeutic agents for the prevention of periodontal diseases - There is scientific evidence that periodontal disease can be prevented and some forms of disease reversed by chemotherapeutic agents. One agent currently available has passed Phase II studies and been approved by the FDA and so is ready for clinical testing in human subjects. The potential of such an agent or similar agents as successful preventive agents would enormously benefit oral health by reducing the burden of highly prevalent diseases that are considered the major cause of tooth loss in adults.

Intra-oral fluoride slow-release device for the prevention of dental caries - The potential of a tooth-sized device implanted in the mouth to provide a constant low level of fluoride would greatly benefit special groups at high risk of developing dental caries. These include handicapped or institutionalized patients, individuals with damage to oral tissues as a result of cancer therapy, and orthodontic patients. Clinical trials would involve several hundred school children.

Composite resins for use in posterior dental restorations - Composite resins have already proven their worth for use as restorations on anterior teeth. Similar composite materials combined with new methods of cavity preparation are ready for testing on posterior teeth where they are subject to greater wear. If successful, such restorations would benefit the public by reducing the amount of tooth substance lost in preparation, improving appearance and possibly reducing cost since less time would be involved in the procedure.

Efficacy of surgical and non-surgical treatment of periodontal diseases - Periodontal disease is the major cause of tooth loss in the adult population. Based on current understanding of the progression of the disease, multiple approaches to treatment have been tested. These include various modalities of non-surgical and surgical pocket elimination, new attachment procedures, and tissue transplantation. The relative efficacy of these methods has never been studied in large scale clinical trials and would serve to clarify issues of paramount importance, both to the practitioner and the public.

NINCDS

Hyperbaric oxygen in the treatment of multiple sclerosis - This clinical trial is designed to establish whether or not treatment with hyperbaric oxygen is effective in modifying the symptoms and cause of multiple sclerosis. Such a study is important because preliminary data and other investigations have indicated that some symptoms of multiple sclerosis are significantly improved following treatment with hyperbaric oxygen.

Copolymer I in exacerbating remitting multiple sclerosis - Copolymer I is a synthetic polypeptide prepared from alanine, glutamic acid, lysine and tyrosine. This clinical trial will evaluate the use of Copolymer I to eliminate exacerbations in patients with exacerbating-remitting multiple sclerosis.

Calcium blockers in the treatment of cerebral vasospasms - The usual cause of death following a cerebral aneurism is cerebral vasospasm. Preliminary reports indicate the efficacy of treatment with calcium blockers to prevent spasms.

Cochlear implant for restoration of hearing - A clinical trial will be conducted to examine the results of the new procedure of implanting electronic devices into the ears of profoundly deaf persons. This procedure will be evaluated along with non-invasive techniques utilizing visual or tactile stimulation. Work will also proceed on the evaluation of a wearable speech microprocessor for patients implanted with a cochlear device.

NIAID

Influenza vaccine - An attenuated, live vaccine represents an attractive alternative to contemporary inactivated vaccines for influenza. Attenuated vaccines are expected to be less expensive and, according to recent data, the resultant immunity is more substantive and longer lasting than that which occurs in response to inactivated antigens. The trial would utilize the cold-adapted vaccine and would seek to determine if such vaccines are an improvement over inactivated vaccines.

Prophylaxis of anaphylactoid reactions - Data indicate cate that histamine release accompanies contrast dye reactions and suggests that it may play a pathogenic role. Other work has indicated that histamine induces hypotension by stimulating H-1 and H-2 receptors. This observation has led to the use of combinations of H-1 and H-2 receptor antagonists in the treatment of anaphylaxis. The trial consists of pretreating subjects who receive contrast media for diagnostic purposes with either a combination of H-1 and H-2 antihistamines or placebo.

Rotavirus vaccine - Rotaviruses have emerged as the single most important worldwide cause of diarrhea in infants and young children and they are an important cause of malabsorption, malnutrition, and fatal dehydration in infants. Several attenuated rotavirus strains have been developed and phase I studies have been started on some. This clinical trial would be an efficacy trial in high risk infants and children.

Immunotherapy in the treatment of laboratory animal allergy - Development of allergy to common laboratory animals is an established occupational hazard. The proposed trial would employ a double-blind placebo controlled design to evaluate the possible efficacy of immunotherapy with epidermal extracts of rabbit, mouse and rat for treatment of allergy to these lab animals.

Gamma globulin treatment of AIDS - All clinical trials underway to repair the immunological deficiency in AIDS patients have been directed at restoration of cell mediated immunity. There is an increased level of immunoglobulin, some of which is directed at microbial agents previously infecting the patient, but the majority appear to be "nonsense" immunoglobulin produced by non-specifically stimulated B cells. We propose to undertake a clinical trial of gamma globulin to provide passive immunity.

Rimantadine treatment of influenza in chronic obstructive pulmonary disease (COPD) - Rimantadine is effective in the treatment or prevention of influenza A infections in normal young adults. However, there is no experimental evidence that this drug is effective in the treatment of influenza infections in persons with COPD. The objective of this trial will be to determine if the therapeutic use of rimantadine will prevent the development of severe lower respiratory disease in these patients.

Monoclonal antibodies in bone marrow transplantation - Bone marrow transplantation with histocompatible donors has been shown to be an effective form of therapy for patients with severe combined immunodeficiency disease, aplastic anemia, some leukemias, and some genetic disorders of marrow function. Graft-versus-host (GVH) remains, however, a major complication of this process and is avoided in less than 40% of the patients. This trial would evaluate the treatment of donor bone marrow and/or the recipient with a monoclonal antibody preparation as a therapeutic agent for controlling the life threatening GVH.

Ribavirin therapy of viral respiratory diseases - Progress in developing control measures for RSV and parainfluenza virus infections has been painfully slow. Attempts at developing vaccines have been unsuccessful thus far. Ribavirin has been shown to have an antiviral effect against a number of viruses, particularly RNA viruses such as influenza, parainfluenza, and RSV. This trial would attempt to evaluate the use of ribavirin in severely ill infants.

Vaccines for Group B Streptoccal (GBS) infections - Epidemiologic evidence indicates that about 12,000 to 15,000 cases of neonatal GBS infections occur yearly in the U.S. Of the survivors, approximately 50% will show signs of neural deficits of varying severity. A vaccine will be administered to pregnant women who are GBS carriers and who have low antibody levels to test whether immunity is passed to the fetus, and thus lower chances of infection during birth.

Monoclonal antibodies in kidney transplantation - Kidney transplantation is a curative and more definitive treatment for end stage renal disease than dialysis. Current medical strategy for kidney transplants includes chemotherapy to suppress the immune system and the use of equine anti-human thymocyte globulin to interrupt rejection episodes. Both of these treatment modalities have attendant problems which need to be overcome. Monoclonal antibodies, specific for human T lymphocyte subsets, would be ideal therapeutic agents for both preventing and interrupting rejection episodes.

NICHD

Efficacy of routine ultrasound screening in pregnancy - Because of the valuable information that ultrasound imaging in pregnancy provides to the obstetrician on possible twins, accurate gestational age, or congenital anomalies, many physicians are advocating its use in all pregnancies. An NICHD consensus conference in 1984 recommended a randomized clinical trial to assess efficacy of routine ultrasound screening.

Clinical evaluation of polylactide microcapsules releasing levonorgesterol - Pharmacokinetic, pharmacodynamic and safety evaluations in which a single injection would be given, which should last for 6-8 months, will test this delivery method as a long term contraceptive. The volunteers would be followed until levonorgesterol is no longer measurable and a normal menstrual cycle is reestablished.

Biological predictors of low birthweight - Several biochemical and physiological measures serve as predictors of low birthweight. These measures will be used as guides to test intervention designed to improve birthweight and pregnancy outcome in a clinical trial.

Efficacy of human surfactant for treating neonatal respiratory distress syndrome - Initial studies supported by NICHD in a few infants suggest that human surfactant may be a highly effective treatment. This possibility needs to be assessed in a clinical trial.

Toxicological, phase I and phase II studies with toluidamine - Although a large number of potential male contraceptives have been investigated, no product has yet been found which completely satisfies the criteria of acceptability, efficacy, and safety. The discovery that 1-substituted indazole-3-carboxylic acids produced strong and specific antispermatogenic effects in rats, monkeys, and dogs has provided a potential lead that should be explored. One of the most active of this class of compounds is toluidamine, which appears to possess a very low level of toxicity based on acute toxicity studies. Further development of this compound must depend on precise characterization of its pharmacokinetics and metabolism in man.

NEI

Treatment of ocular melonoma - Ocular melanoma has a high rate of metastarsis to other body sites, and is associated with a death rate of 50 percent within five years. The standard procedure has been to remove the cancerous eye. Recently developed techniques of ion-beam irradiation will be compared to exenteration of the eye in a clinical trial to determine whether this technique is equal, or possibly more effective in prolonging both vision and life.

Treatment of uncontrolled glaucoma with 5-fluoruracil - Uncontrolled glaucoma (i.e., unresponsive to pharmacological treatment) is usually treated with a surgical procedure which increases the flow of the intraocular aqueous fluid, thereby reducing intraocular pressure and the risk of visual loss. The normal healing processes within the eye often result in fibroblast proliferation and surgical failure. The objective will be to determine if 5-fluorouracil is effective in reducing the rate to blindness in these high risk glaucoma patients, without untoward side effects.

Antimicrobial and anti-inflamatory agents in the treatment of retinal disease - Clinical trials of Cyclosporine A are currently being conducted in the NEI intramural program in an attempt to reduce the blinding effects of uveitis, an autoimmune disease of the eye. Additional studies will be conducted on the efficacy and safety of other immunosuppressive agents for the treatment of blinding ocular inflammatory diseases.

Cryotherapy treatment for acute retrolental fibroplasia - Low birth weight premature infants are at high risk for the disorder. Procedures have recently been developed for identifying those infants most likely to develop the blinding form of this disorder. In this clinical trial, the efficacy and safety of retinal cryotherapy for the prevention of blindness in these high-risk infants will be evaluated.

Treatment of retinal detachment - Retinal detachments often occur as a consequence of "massive periretinal proliferation," a bleeding and traction within the eye which results from vascular eye diseases or ocular injuries. Standard retinal reattachment surgery has a low rate of success; the periretinal proliferation returns in well over half of the cases. Techniques have recently been developed for using a silicone gel to keep the retina in place, at the same time blocking periretinal proliferation and subsequent retinal detachment. The relative safety and efficacy of silicone implants in the preservation of vision will be evaluated.

Steroid treatment of optic neuropathy due to Grave's disease - Optic neuropathy occasionally occurs in patients with Grave's disease due to the compression and ischemia of the optic nerve associated with this condition. In the severe form, irreversible blindness ensues. This controlled clinical trial will evaluate the potential of steroid treatment for the reduction of visual loss.

Comparison of intracapsular and extracapsular cataract extraction - More than 500 thousand surgical procedures are performed each year for removal of cataractous lenses, the third leading cause of blindness in the United States. There are two major variations of this surgical procedure. In one, intracapsular extraction, the lens is completely removed. In the second, extracapsular extraction, the posterior capsule of the lens is left inside the eye. Both procedures have been highly refined, yet each has its benefits and its problems. This project will provide the first comprehensive comparison of the efficacy and safety of these two procedures.

Evaluation of visual correction following cataract extraction - In recent years, a number of new lens technologies have been developed, to obviate the need for the heavy glasses that were once the hallmark of cataract extraction. The techniques include methacrylate lenses placed inside the eye during the cataract surgery, as well as various forms of contact lenses which can be worn for extended periods of time. Still newer techniques have been developed for modifying the shape of the patient's own cornea (the outer lens of the eye itself). This study will compare the safety and efficacy of these various methods of optical correction following cataract surgery.

Drug treatment of strabismus - Investigators have demonstrated that minute amounts of Botulinum toxin can be used to weaken selected extraocular muscles, and to reduce the eyemuscle imbalance associated with strabismus ("cross eyes" or "wall eyes"). Since the long term effectiveness and safety of the procedure remains to be demonstrated, a clinical trial is being planned to compare this technique to conventional surgery and optical treatments.

## INSTITUTE OF MEDICINE STUDY

Question: The Institute of Medicine is conducting a comprehensive study of the organizational structure of NIH. What is the status of the IOM study of NIH--and when will it be finished?

Answer: The three panels established by the IOM to address major aspects of the study have completed their fact-finding and have submitted reports to the IOM Steering Committee. The Steering Committee has outlined its main report and will be meeting through July to draft, review, and finalize a draft of its report for internal review. The final report will be completed in late October 1984.

Question: How soon would you expect to take action on its recommendations?

Answer: The NIH will act upon the recommendations in a timely fashion. The timing will, of course, depend upon the nature of the recommendations and the extent to which it would be helpful and necessary to consult with the health research community, Congress, Federal health agencies, professional societies, and health organizations in evaluating and responding to the report's recommendations.

## RESEARCH IN AIDS AND ALZHEIMER'S DISEASE

Question: Congress made quite a point last year of its desire for progress against certain diseases, especially acquired immune deficiency syndrome (AIDS) and Alzheimer's disease. Please bring us up to date on the battle against these diseases. Is there any hope of finding a cure or preventative approach any time soon?

Answer: Within the NCI, two thrusts are of major importance regarding AIDS. The first is to establish clear causality for retroviruses in human AIDS. The role of a retrovirus in simian AIDS is quite likely at this time. So far, the probability of an HTLV-like agent causing human AIDS is a promising lead. Data in selective HTLV antibody positivity of AIDS patients but not in their matched controls, data on HTLV association in transfusion-associated AIDS cases as well as in hemophiliacs, and recent findings of high HTLV positivity of Haitian mothers of children with AIDS strengthen the causal supposition. If such retroviral agents or variants are established as causative, then prevention methods can be considered in the form of vaccinations to specific viral proteins in the at-risk population. The other NCI effort is the search for biological modifiers, such as various lymphokines, responsible for the growth of T helper cells, which would reverse the invariably and progressively deteriorating immunological status. Interleukins and other substances which now can be obtained in adequate amounts in cloned form should be tried.

The NHLBI recently awarded grants in support of investigator-initiated research aimed at the development of a test for the carrier state in AIDS, which could be introduced into the Nation's blood banking system should it ever prove necessary to screen blood donors who may be carriers of the disease. In addition, the NHLBI is supporting a long-term multicenter investigation that will provide for the study of the recipients of blood or blood products from donors subsequently found to be at greater than average risk of contracting AIDS. This epidemiological information may provide not only evidence as to the risks associated with blood transfusions, but possibly, clues of value to those investigators seeking to identify the etiological agent of AIDS.

Included in the search for the etiologic agents of AIDS are efforts such as the NIAID contract with the New York Blood Center to collect specimens from various groups of individuals considered at risk of acquiring AIDS. The samples will be collected, catalogued, and stored. When individuals in the study develop the disease, the stored specimens will be examined for the presence of various microbial agents and for antibodies to various agents. In addition, five other contracts have been awarded around the country. Aliquots of specimens from each of these contracts will also be stored at NIH so that searches for etiologic agents can be performed in NIH laboratories as well in the laboratories of the individual contractors. This massive examination of prospectively acquired specimens holds great promise for elucidation of the etiologic agent.

Another promising area is in the treatment of AIDS with hormone-like substances of the immune system such as interferon and interleukin-2. Active clinical studies are underway in clinical testing of these experimental compounds. It is clear that they have some type of effect on the immune system, and it is hoped that these studies will reveal that the use of these hormones does benefit AIDS patients.

At present, there are several promising areas of research concerning the cause of Alzheimer's disease. Among these are investigations as to why certain neurotransmitters are diminished in

Alzheimer's disease. Another important question that needs to be answered is why nerve cells die in specific parts of the brain controlling memory function and learning ability. The possibility that an infective agent such as a slow virus may cause the disease has attracted wide attention. The role of metals, such as aluminum, in the environment continues to be an area of active research.

Concerning diagnosis, the development of more accurate, specific, and sensitive neuropsychological test batteries is one of the most promising areas of research. Nuclear magnetic resonance promises to be an effective noninvasive diagnostic technique. PET (Positron Emmission Tomography) has already shown some remarkable results in our ability to differentiate between normal brain functioning in healthy aged people from those with Alzheimer's disease, as well as conditions that lead to brain degeneration.

With respect to treatment, some of the drugs that increase the ability of nerve cells to synthesize and release more neurotransmitters or inhibit the breakdown of these substances appear to provide some promise for ameliorating the symptoms of Alzheimer's disease in the early stages. In very early experimental stages, work is underway with brain tissue transplant techniques using animal models. Such studies have shown that it is possible to ameliorate brain dysfunctioning related to deficits of specific neurotransmitters.

Concerning prions, it has been shown in animal studies that this infectious agent has similar characteristics to amyloids. Amyloids are found in Alzheimer's disease as well as other degenerative diseases of the brain. If this study is replicated and the evidence corroborated, we would have an important clue about the possible structural characteristics of an infectious agent, and will have demonstrated a link between infectious virus and amyloids. The implications would be that diseases such as Alzheimer's could be caused by an infectious agent.

Question: We understand that monkeys have been infected with AIDS. What has been the usefulness of this sort of experiment?

Answer: Animals and animal models have played an important role in the development of prevention and therapy for infectious diseases since the beginning of modern medicine; for example, smallpox, tuberculosis, polio, and recently hepatitis B. Establishing an animal model has been a major step in the progress to control most human illnesses.

The diseases animals share with man such as rabies and tuberculosis provided direct approaches for laboratory studies. Diseases such as polio and hepatitis B that were not obviously shared with animals were more difficult to study. Many inoculations of many species of animals, often under special conditions, were required to establish a system that could be used under controlled laboratory conditions.

AIDS appears to be an infectious disease. Standard laboratory methods for microbial isolation and identification have been tried and as yet have not consistently identified an agent as the cause of AIDS. Animal inoculations using the methodologies of former successful searches are imperative. They are proceeding in a variety of species.

The chimpanzee is one of the most important species being used, as it was in the polio and hepatitis studies. The use of chimpanzees in research of this type is done with much thought and planning. Chimpanzees are used only in well-designed, carefully planned studies for which the chimpanzee offers unique advantages over other laboratory animal species. Based on information regarding the highly successful use of chimpanzees in hepatitis research, which led to a vaccine, the chimpanzee may well be the key for identification of the etiologic agent of AIDS. Attempts to transmit this disease to other laboratory animals (including mice, hamsters, guinea pigs, and rabbits) have been unsuccessful. Consequently, it is highly appropriate and fully justified, at this point in time, to attempt these studies in chimpanzees. Use of the chimpanzee has the potential for making significant contributions toward the solution to this important health problem.

NCI is supporting two projects that utilize simians in an attempt to develop an animal model for AIDS. One project is attempting to transmit AIDS occurring in monkeys to immunodeficient mice, and from affected humans to monkeys and immunodeficient mice. Virological studies will place particular emphasis on the isolation of the disease-producing agent.

The other NCI project is using captive rhesus monkeys with spontaneous simian acquired immune deficiency syndrome (SAIDS) with Kaposi's sarcoma-like lesions, which has proven readily transmissible to other monkeys in the colony, but not to rodents. It is now reasonably clear from a number of laboratories investigating SAIDS that the causative agent is a "D" type retrovirus. This virus is a new isolate that has not been previously described. Thus the rhesus model can be used to determine whether early diagnosis and prevention will be feasible. These findings have also been helpful in eliminating other infectious agents which have been postulated in the causality of this disease.

The NIAID intramural program has done experiments in which approximately four chimpanzees have been injected with material from AIDS patients. So far there has been no evidence of infection or disease as a result of receiving these materials. Smaller primates are also being used in AIDS studies because of the observation of a disease in several primate colonies which shows some similarities to human AIDS.

Question: We note you are conducting therapeutic trials in an attempt to restore the damaged immune system in AIDS patients. What have been the results to date?

Answer: The NIAID Intramural Research Program has been involved in four treatment protocols using various approaches to the reconstitution of the immune system in AIDS patients. One protocol involved the attempted immune reconstitution using bone marrow transplantation to an AIDS patient from his identical, healthy twin. Although there appeared to be clinical and immunologic improvement, the patient died of pneumonia. No similar opportunity has recurred.

Two other protocols involve the use of the immune system hormone-like substances, interferon and interleukin-2, for the treatment of AIDS. Both of these compounds have clearly caused some improvement in the immune systems of patients; however, it is too early to say if treatment of AIDS with interferon or interleukin-2 will completely restore the immune system to normal. These studies are being continued and are being expanded to a limited degree.

The fourth NIAID treatment protocol involves the use of plasma exchanges to remove possible suppressor substances from the blood of AIDS patients. One patient was begun in FY 1983, and there are plans to add additional patients to this protocol. No clear results are available at the present time.

Question: What new drugs are you working with that give hope of providing treatment for victims of Alzheimer's?

Answer: There is much scientific evidence indicating that Alzheimer's disease may be due to the premature degeneration of brain cells that employ acetylcholine as a transmitter. This has led to therapeutic trials of drugs that may increase the content of acetylcholine in the brain or prevent the breakdown of this transmitter substance. To date, however, none of the therapies tested has proven effective when evaluated in a large scale, well-controlled clinical trial.

However, there are two drugs in the experimental stages that may prove to be of some benefit to the victims of Alzheimer's disease. A drug called 3, 4-diaminopyridine has been shown to improve the memory of aged animals. The other drug, known as pentoxifylline, which improves the oxidative metabolism of brain tissue, has completely reversed the striking impairment in maze-learning ability of aged animals.

As these and other promising agents emerge, we anticipate that clinical investigators will be evaluating them. Unfortunately, at the present time, no effective drugs or other therapies are available for this illness. It appears that further study of the basic mechanisms and pathogenesis of Alzheimer's disease will be required before we can expect useful treatment to become available.

## INDIRECT COSTS

Question: We note you are not back with another effort to cut indirect costs of research. What ever happened to the idea about having the President's Science Advisor conduct a study and provide recommendations about this matter? Or should we simply put the issue in the category of "too hot to handle--don't touch"?

Answer: The idea about having the President's Science Advisor take the lead in developing and coordinating a government-wide solution to the indirect cost problem is still very much alive. The Secretary has formally requested the President's Science Advisor to do precisely that. In response, Dr. Keyworth has recently agreed to have the White House Office of Science and Technology Policy coordinate a government-wide approach both to the indirect cost problem and to the wider issues of grant and contract policy and university infrastructure.

Question: What is your estimate of the fiscal 1985 amount needed for indirect costs?

Answer: Total indirect costs for NIH research grant awards in 1985 are estimated at $947 million, or 31.6 percent of total costs.

STAFF CUTS/CONTRACTING OUT

Question: The Subcommittee notes that you plan to cut your staff by 588 positions--from 13,595 to 13,007. Why would you make such a cut and which activities would bear the burden of the reduction?

Answer: You are correct; the budget request includes a decrease of 588 full-time equivalents (FTEs), from 13,595 in 1984 to 13,007 in 1985, or a reduction of 4.3%. This proposed reduction is a part of the President's efforts to reduce the size of Government and increase its efficiency. The Department of Health and Human Services is taking an overall 5% cut--or 6,876 FTEs.

We, like all other Government agencies, are making a strong effort to make management improvements that will allow us to operate efficiently with a reduced staff. For example:

o We are making good progress in computerizing many of our administrative functions and have already made some manpower savings in doing so.

o We are working with the Assistant Secretary for Personnel Administration, Tom McFee, to reduce FTE requirements for personnel services.

o In accordance with OMB Circular A-76, which states the Government's general policy of relying on the private sector to supply many of our service needs, we have a number of activities under study to determine if it would be cheaper to contract for them; e.g., housekeeping, graphic arts, glassware and media preparation.

o Finally, FTE savings could be achieved by either eliminating or reducing the size of our summer employment program.

The reductions will come primarily from three areas: 146 FTEs in administrative staff and staff associated with managing the extramural programs; 207 FTEs in central services such as police and fire protection, procurement, maintenance, and clinical services; and 235 FTEs in the intramural research program.

Question: Since you are, in the jargon of the bureaucrat, cutting full-time equivalent positions, how many people will be affected by the reduction? More than 588?

Answer: In order to cut 588 full-time equivalents (FTEs), we estimate that approximately 800 to 1,000 positions would be affected out of a current on-board of about 14,100. This estimate will remain sketchy until the plan for implementing the FTE reduction becomes final.

Question: You also are examining the possibility of contracting out some of your work as ordered by OMB. Why, for example, would you want to contract for fire department service? Don't you have a veteran fire department out there and aren't they well acquainted with your fire safety needs and problems?

Answer: When Circular A-76, "Performance of Commercial Activities," was issued by the Office of Management and Budget, the Circular identified "fire protection and prevention services" as a specific example of a commercial activity. Because NIH has such an activity, a very specific cost comparison study was initiated as specified by the Circular to determine the most economic method of performance.

It should be noted that activities identified as commercial industrial activities do not automatically become subject to contract. In order for an activity to be transferred from an in-house operation to a contract operation, it must be determined that a satisfactory commercial source is available and that contractor cost performance would be at least 10-percent more cost effective than that of in-house operation.

Specifically concerning the NIH Fire Department, our recent solicitation of interested contractors did not receive any responses, so in-house performance of this activity will be continued. We would agree that our veteran Fire Department is well acquainted with NIH's fire safety needs and problems.

## ADMINISTRATION OF NIH

Question: Dr. Wyngaarden, you were sworn in as Director in June 1982. You are now confronted with many pressures to expand substantially the NIH establishment and to recognize certain facets of that establishment. Could you discuss those problem areas in the administration of NIH that are of greatest short-term and long-term concern to you?

Answer: Stated in the simplest possible terms, we need to assure adequate levels of support for the entire research enterprise if we are to preserve the momentum of discovery. While the most important component of our program mechanisms is the research project grant, it is necessary that balance be maintained among the essential mechanisms for research support. In speaking of the essential mechanisms for research support, I would include at the minimum adequate funding for centers, for contracts, for intramural research and for training, as well as for research grants. Another matter requiring attention is the need to replace or purchase the increasingly sophisticated instruments required for today's research. The NIH has recently joined an ongoing study by the National Science Foundation for the purpose of securing a valid current assessment of national need.

Extramural laboratories and facilities are slowly deteriorating. With the exception of funds supplied by the Cancer Program and more recently by the National Eye Institute, NIH stopped supporting facilities after 1969 and currently lacks legal authority to do so. As a consequence, many of the facilities benefiting from the major NIH construction effort are more than 20 years old, or are rapidly approaching that mark.

As important as buildings ,and adequate instrumentation may be, there is another consideration of even greater moment. That subject is research training. In our view, the training and research programs are so closely interwoven as to be practically indivisible. During the coming year, we expect to devote substantial amounts of time in efforts to improve the effectiveness of our research training programs.

Question: To what extent is NIH insufficient in size to meet its requirements? Are there improvements in the administrative design of NIH that you would personally favor?

Answer: There are increasing pressures on the NIH for the creation of new organizational entities, each having a relatively narrow focus on a particular set of health problems. Such movements gain much of their strength from and indeed are an expression of the public confidence in the power of research. The movements are also an understandable reaction by segments of the biomedical community to the funding crunch and represent an effort to establish altered research priorities through congressional action.

The NIH and the Department of Health and Human Services have opposed legislation for creation of new Institutes and for the establishment in statute of favored status for specific research programs. Our opposition to these proposals is based not only on their adverse effects on administrative costs and flexibility, but also because the compartmentalization they establish is counter to the direction in which science is moving. At a time when we can confidently predict unusually rapid movement in science but cannot predict just where that progress will occur, we need the maximum flexibility for marshaling finite resources for the support of science. Organizational structures have a direct influence on funding priorities.

Last June, we asked the Institute of Medicine of the National Academy of Sciences to make an objective study of the organizational structure of the NIH and, considering scientific developments and economic conditions, to recommend the establishment of standards for determining the need for any substantial change in the organizational structure of the agency. We expect the study to be completed and to have a report from the IOM in November 1984.

Question: What is your reaction to legislation that would create a National Institute of Nursing at NIH?

Answer: The Assistant Secretary for Health, Dr. Brandt, testified before the Senate Committee on Labor and Human Resources on March 14, 1984, in opposition to the creation of an NIH National Institute of Nursing for several reasons. Nursing research is currently well integrated into the PHS agencies and programs in which it has been operating, and significant changes would be disruptive.

The NIH Division of Research Grants refers research proposals, as appropriate, to components of the NIH, the HRSA's Division of Nursing, the National Center for Health Services Research, or other agencies. Research problems of mutual interest to two or more agencies are carried out jointly. In addition, there is consensus that one of the highest priority needs in nursing research is strengthening the research base in schools of nursing and increasing the number of doctorally trained nurse researchers and educators. This can best be accomplished in programs closely aligned to nurse training and education, as is the case with the current structure.

As mentioned in the answer to the preceding question, the NIH contracted in 1983 with the Institute of Medicine of the National Academy of Sciences to conduct a study of NIH's organization. Because this comprehensive study of NIH is ongoing and will be completed shortly, it is premature to make major organizational changes at NIH at this time. Indeed, we believe that to make such changes may work at cross-purposes to the intent in initiating this study; i.e., to attempt to determine, with input from the scientific community and with the best available scientific and managerial expertise, the most appropriate organization of this major research agency.

NIH has recently established a nursing research task force to examine NIH support of this area and to consider the best approaches to such support within the context of the NIH mission. This is part of a PHS-wide effort, which is focusing on ways to expand knowledge about nursing practice and administration as well as strengthen the infrasturcture of nursing research.

In light of these activities, we believe that legislation that would establish an Institute of Nursing is premature, effectively preempting the serious and thorough consideration being given to this matter at the present time.

The Department is currently looking at various approaches to strengthen nursing research in the Public Health Service. The options currently under consideration include further strengthening of the programs in the Division of Nursing in the Bureau of Health Professionals (including the nursing research function), and changing the current Division of Nursing to a Bureau. Other options are also under review; a decision is anticipated by the end of the fiscal year.

In addition to these organization/administrative options, PHS is also researching, within the context of existing resources, budgetary needs in nursing research.

## ROLE OF NURSES

Question: In our fiscal 1984 report, the Committee once again directed NIH to make a concerted effort to increase the participation of nurses in NIH programs. In its response, NIH said it is aware of the Committee's concerns and "will take the actions appropriate to address the issue." What specifically have you done to address the Committee's concerns and what "appropriate" actions do you have in mind? What meetings, conferences and analyses were conducted or other actions taken during the year to set in motion a positive response to the Committee directive?

Answer: Several activities are underway. In 1983, the National Institute on Aging (NIA) and the Division of Nursing (DN) of the Health Resources and Services Administration developed an announcement of their desire to fund clinical trials of behavioral therapies for urinary incontinence in the elderly. The announcement was issued March 2, and applications are due May 20. The serious and costly health care and nursing practice problem of urinary incontinence is of great interest in both NIA and DN. The administrative and funding mechanism used to support the clinical trials will be a cooperative agreement between each of the awardees and NIA/DN. There will be substantial programmatic involvement of NIA and DN staff in the projects. This approach illustrates how the lead biomedical research agency and the agency with principal responsibility for the support of nursing research can combine their individual responsibilities and expertise in working together to solve a problem of interest to both.

In March 1984, an NIH Task Force on Nursing Research was established as part of a PHS-wide effort to examine possible approaches to strengthening nursing research. The NIH Task Force is charged to assess the extent to which NIH has and can support biomedical research conducted by nurses, and nursing research consistent with the NIH mission. The task force will also examine the current and potential role of nurses on NIH advisory and review committees. A report from this task force is expected in 6 months and will comprise part of the PHS deliberations on this issue.

NIH review and advisory committees are responsible for assuring that we conduct and support research programs of the highest quality, and of significance both to scientific opportunity and public need. Individuals with backgrounds in nursing, nursing education, and nursing administration can play an important role in such an evaluation process.

The NIH has participated actively with professional groups such as the American Nurses' Association to identify nurse researchers who might be considered for service on appropriate NIH advisory committees. The associations have provided the NIH with names of qualified individuals. These names are given wide distribution within the NIH, are referred to the appropriate Institute Directors for their consideration, and are circulated to other relevant Public Health Service agencies. In addition, these individuals are invited to have their names included in the NIH's file of potential advisors and consultants. The information will be included in the NIH Consultant File, a computerized registry of potential advisors and consultants to be considered not only for committee membership but also for other peer review activities, such as site visits.

## MANAGEMENT IMPROVEMENTS

Question: Your budget request assumes savings of $4.1 million through "management improvements." You seem to focus on cutting printing costs and making reductions in the average grades of your employees. Please give us a fuller idea of how you plan to achieve these savings. Are you really saying that your approach will be to give everything a pro-rata cut?

Answer: The full details have yet to be worked out, but the Administration is confident that these savings can be accomplished through Reform '88 and other management improvement programs. Besides analyzing the printing operations for possible savings, we are studying the utilization of private sector contractors to provide other support services where appropriate and economical, and the centralization to some degree of personnel services to effect these savings.

The program to reduce the average grade as well as the total number of GS-11 through GS-15 positions is known as "Project Bulge."

Positions that become vacant will be reviewed to determine if they can be refilled with lower grade employees, which will result in savings without downgrading employees already on board.

## FIVE-YEAR PLANNING FOR RESEARCH

Question: In October 1978, a National Conference on Health Research Principles was held at NIH to bring together biomedical research leaders for a discussion of new directions for basic research. Principles for a five-year plan were developed. What has happened to former Director Donald Fredrickson's proposal to develop a set of principles for establishing a five-year plan of research?

Answer: The purpose of the conference was to develop a set of principles to guide the HHS in its conduct and support for health research programs, rather than establishing a five-year plan of research. Based upon the set of principles developed at the conference, special interagency health research initiatives were established. These were widely reviewed, sent out for public comment, and since then have been incorporated into the planning structure of the appropriate agencies and NIH Institutes. Some of the initiatives in which the NIH plays a principal role are the stabilization of research project grants, the National Toxicology Program, Alzheimer's disease and dementias of aging, nutrition research, and the accelerated development of new vaccines.

## RESEARCH EQUIPMENT AND INSTRUMENTATION

Question: During the FY 83 hearings, NIH reported to the Congress on shortages in research equipment and instrumentation. What is being done to redress this problem, and has it gotten better or worse?

Answer: In 1984, the NIH is increasing its support for instrumentation through several different mechanisms. To support the needs of research projects in areas of interest to the National Institute of General Medical Sciences, that Institute awards supplemental funds to provide shared instrumentation. The Biotechnology Research Program of the Division of Research Resources provides support to assure the development and availability of high technology instruments, to be shared on a regional or national basis. Shared instrumentation grants provide for state-of-the-art equipment to be shared within Institutes. The Minority Biomedical Research Support grantees receive shared instrumentation through supplemental funding. Research project grants provide for relatively inexpensive equipment that does not lend itself to shared usage. Funding for the various instrumentation programs, as well as estimates for equipment provided through research grants, are shown on the following page:

Instrumentation Programs
(dollars in thousands)

| | 1983 Actual | 1984 Estimate | 1985 Estimate |
|---|---|---|---|
| General Medical Science | $ 671 | $ 255 | $ 255 |
| Division of Research Resources: | | | |
| Biotechnology Research | 20,204 | 27,393 | 27,677 |
| Shared Instrumentation Grants | 14,000 | 19,770 | 19,770 |
| Minority Biomedical Research Support | 1,000 | 1,000 | 1,000 |
| Subtotal, DRR | 35,204 | 48,163 | 48,447 |
| Total, NIH | 35,875 | 48,418 | 48,702 |

Equipment Provided by Research Grants
(dollars in thousands)

| | 1983 Estimate | 1984 Estimate | 1985 Estimate |
|---|---|---|---|
| Total, NIH | $45,500 | $51,700 | $54,000 |

With regard to future instrumentation needs, we are cooperating with the National Science Foundation in a study of these requirements. This study is expected to be completed and available by April 1985.

## CLINICAL CENTER MODERNIZATION

Question: What is the status of your multi-year project to modernize the Clinical Center? Is it on schedule?

Answer: The Clinical Center renovation project is in its seventh year and, for the most part, is on schedule. There is some slippage due to difficulties in interfacing various programs with the construction and renovation schedule and in altering plans to meet program needs.

Question: Have you had to defer portions of the project because of budget restrictions?

Answer: The Clinical Center Modernization project is a 10-year project for which funds have been available since its inception in 1979. Progress on the project has been maintained and has not been hindered by financial restrictions. Any deferrals of work that have occurred are more the result of unforeseen scheduling difficulties inherent in a project of this size rather than the unavailability of funds.

## IMMUNOLOGY RESEARCH

Question: The subcommittee was very interested in your special report on immunology research which has such broad application at NIH. Where do we stand in the effort to understand the immunological system--are we well along in the effort, or do we have a long way to go?

Answer: As indicated in the report, the explosive growth of interest and activity in immunology has led to considerable progress. Advances in our understanding of the fundamental molecular and cellular mechanisms of the immune system as it functions in health and disease are providing exciting new leads. We are just beginning to comprehend the complexity of the interactions between the cellular elements of the immune system, of the immunoregulatory effects of their products, and of the genetic influences on the system. We still need much more insight into the nature of involvement of the immune system in disease.

Question: What steps do you take to make certain all parts of NIH know what each of the other parts are doing--and what progress they are making--in the field of immunology?

Answer: As noted in the report, extensive cooperation and coordination exists among the NIH Institutes in their support of immunology research. This includes scientific collaboration between intramural scientists in different Institutes, cooperative sponsorship of workshops and data banks, joint solicitation of immunology research projects, transfer from one Institute to another of pending research grant applications, joint extramural funding by two or more Institutes of research contracts and conference grants, and extensive sharing of research reagents and results.

The report gives specific examples including topics discussed at the weekly "NIH Immunology Seminar," which is composed of intramural scientists from the NIAID, NCI, NIADDK, NIDR, NICHD, NEI, and NINCDS, who meet to exchange the latest information on their experiments. The report also gives examples of the many scientific papers resulting from collaboration between intramural immunologists from different Institutes.

The report discusses the "NIH Acquired Immune Deficiency Syndrome Scientific Working Group," which is composed of representatives from the Office of the NIH Director, NIAID, NCI, NICHD, NHLBI, NIDR, NIEHS, NINCDS, NEI, NIADDK, DRR, FIC, the NIH Clinical Center, and the National Library of Medicine. The responsibilities of this group are to foster exchange of information among the Institutes at NIH and to provide a ready channel to make current research findings available to the Centers for Disesae Control and other agencies that may be involved in control of AIDS.

## TRAINING GRANTS

Question: NIH relies on the National Research Service Awards but there currently is no authorization for this program. What has been the effect of the lapse in authorization of the National Research Service Awards?

Answer: The lapse of authorization resulted in support of the program through a continuing resolution in 1984 for the NRSA's. The continuing resolution provided support at approximately the same funding level as the 1983 estimated actual dollar level. This level will support an estimated 9,863 trainees, 700 fewer than 1983.

Question: In confronting budgetary restrictions, what priority do you give to your training grants programs and why?

Answer: Support for the NIH research training program is second only to our commitment to funding 5,000 new and competing investigator-initiated research project grants. The preparation of investigators is the foundation on which the future of tomorrow's research success depends. Despite budgetary constraints, we have included a 5-percent increase in stipends; while marginal, this action should help attract well-qualified predoctoral and postdoctoral trainees to research careers.

The research training program is the essential element in the future of biomedical and behavioral research. Investigation and the transfer of laboratory findings from the bench to the bedside are dependent on the availability of trained investigators. The NRSA supports the critical mass of scientists in training who will develop and provide the knowledge to be applied to prevention and treatment of disease, thus decreasing the emotional and economic costs of illness.

## TROPICAL DISEASE RESEARCH

Question: Relatively small amounts of money are budgeted for tropical disease research. The research is being done in discrete units among several Federal agencies, as well as in some universities. Although there is informal coordination between researchers on related projects, could this be done better to maximize and accelerate the research effort? Would it be useful to have a set of goals and objectives at the national level for research and action on international health problems? Could the NIH play a role in this?

Answer: Support provided by the National Institute of Allergy and Infectious Diseases (NIAID) for Tropical Disease Research (TDR) programs, including the six WHO-targeted tropical diseases, general parasitology, and general tropical medicine, totaled $33.4 million in 1983, or 12.6 percent of the total NIAID research and training budget. Over 90 percent of NIAID's grants and contracts for TDR are awarded to domestic research institutions. The vast majority (99%) of these awards are in the form of competitive investigator-initiated grants. Under the grant mechanism, the publication of research results ensures wide dissemination of scientific information and open scientific exchange. NIAID frequently convenes meetings of national and international (including third-world) scientists for discussion of developments in specific areas of tropical disease research, and therein plays an active role in supporting interaction and coordination among tropical disease researchers.

Each major agency involved in international health problems, such as NIH, AID, DOD and the Department of State, have somewhat differing goals and objectives and thus a set common to all would not be practical. However, many of the goals are shared or are mutually reinforcing, and close coordination is important. Such coordination is maintained through a variety of mechanisms. For example, scientists of one agency sit on peer review or advisory bodies of other agencies. Vaccine development, for another example, has an interagency board which convenes regularly and is chaired by an NIAID senior staff scientist. We feel that our respective interests in international health problems are being adequately served, and we can look to the World Health Organization to provide an appropriate level of global oversight.

Question: Is the amount of funding or the number of grants for tropical disease research, as a whole or in particular areas, based on criteria other than scientific merit, such as usefulness or benefit to the U.S., humanitarian need, importance to the protection of U.S. health, or importance to U.S foreign policy? Does the worldwide value get factored in? If some policy exists, is it formal or informal?

Answer: In accordance with NIH policy and mandate, NIH grants are awarded primarily on the basis of scientific merit. Other factors, such as benefit and usefulness to the United States, are not taken into account in the primary scientific merit review of tropical disease research proposals. At the secondary review level (National Advisory Council and the NIAID Director) programmatic considerations other than scientific merit are evaluated and decisions are made on a case-by-case basis.

Question: Are you aware of changing emphases in the study of tropical diseases, such as one etiologic agent or syndrome with decreased activity and another enlarged activity, as evidenced by number of grants, researchers, or funding? Is this evaluated in any way?

Answer: Changing emphases in the study of tropical diseases are monitored on a regular basis and reflected in NIAID's annual report on tropical medicine and international research activities. The current trend is toward cutting back on targeted biomedical research and training in favor of investigator-initiated grants.

Question: In international health and tropical disease research, is there any increase in cooperation between the government and the for-profit companies? Is there any trend toward more contracts for the private sector to carry out research?

Answer: It should be pointed out that for-profit companies usually do not invest heavily in R&D in drugs, vaccines, or biologicals for tropical diseases because of the potentially limited commercial market.

Question: How does the U.S. compare to other countries in terms of spending or other measures of activity in tropical disease research? Is the U.S. doing as much as Japan, the Soviet Union, England, Germany, France, Sweden, Holland, or Cuba? Does the U.S. draw unfavorable comparison in the international community? Is an opportunity to advance U.S. foreign policy and image in a benevolent way being squandered?

Answer: The United States compares very favorably to other countries in terms of support for tropical disease research. U.S government agencies (DHHS, USAID, DOD) and U.S. private foundations (Edna McConnell Clark, Rockefeller) contribute more toward tropical disease research programs, domestically and abroad, than any other nation. Japan and many Western European countries are effective in coordinating their domestic biomedical research agencies and university activities with their international assistance and development programs. The USSR and Cuba produce highly motivated health service professionals but support little tropical disease research. It should be pointed out that NIH participates in bilateral science and technology initiatives with all the above countries with the exception of Cuba. A more extensive U.S. domestic and international tropical medicine research effort would undoubtedly improve the U.S. image.

Question: Should the U.S. have an explicit foreign policy objective of carrying out tropical disease research, supplying medical and health professionals, and health aid (for example, as the government of Cuba does)?

Answer: U.S. foreign-policy-making institutions (the Department of State and USAID) should address questions regarding foreign policy objectives. NIH is not a foreign policy-making body and is not the appropriate agency to answer questions concerning an explicit foreign policy objective of carrying out tropical disease research or supplying medical and health professionals and health aid.

Question: How does NIH, especially NIAID, view its responsibility to get results of research out into practice? Is transfer of knowledge/technology consciously promoted, especially to less developed countries which do not possess the internal resources for advanced research and which do not have the ability to learn about advances as quickly as desirable?

Answer: NIAID's primary mission is to support domestic research. Scientists get peer recognition by the originality, quality, and number of scientific articles published. This is a great incentive for investigators to publish results rapidly. Thus, advances in research are made available in a timely manner for everyone to use. The transfer of knowledge and the development of technology for the developing countries is the responsibility of USAID and WHO. NIAID continues to work with counterparts in USAID to facilitate and accelerate the transfer of knowledge/technology by providing technical advice (e.g., on malaria vaccine developments). NIAID frequently includes scientists from developing countries at scientific meetings convened by NIAID.

Question: What research is taking place at NIAID on immunization against tropical diseases?

Answer: NIAID is the PHS entity responsible for the accelerated development of vaccines. Among the tropical diseases, NIAID supports research on the development of vaccines for malaria, leprosy, schistosomiasis, and diarrheal diseases (cholera, thyphoid fever, and rotavirus) as well as more basic research on the respective organisms and disease processes that may eventually lead to new insights into improved and safer vaccines.

Question: In relation to research towards a malaria vaccine, if an efficacious vaccine is developed, what problems does NIH see in the manufacture and supply of it? Will the commercial production pose problems with regard to ownership of patent rights?

Answer: There are potentially three different types of malaria vaccines that could be developed: a) sporozoite; b) asexual; and c) gametocyte vaccines. At present, the NIH, various research institutions in Europe (e.g., Pasteur Institute), and several multinational pharmaceutical firms (e.g., Welcome, England) are heavily involved in the development of sporozoite and asexual vaccines which would protect individuals from malaria. The gametocyte vaccine would block transmission of disease in the mosquito. Because the protective gametocyte antigen has not been identified, this vaccine is further behind in development. NIH does not foresee any problems with the manufacture or supply of the sporozoite or asexual vaccines.

## TUBERCULOSIS RESEARCH

Question: Tuberculosis is a worldwide health problem. In the U.S. too, in spite of large gains against the disease, TB has plateaued as a persistent public health problem with incidence no longer declining (due to epidemiologic and demographic factors). Does NIH/NIAID have a role to play in this current problem? What research is in progress or planned?

Answer: NIH/NIAID has a very distinct role to play in support of research on TB. The Institute promotes research on TB and on the other related but not identical strains of non-tuberculosis mycobacteria through the award of research grants and contracts. Tuberculosis research is also a component of the U.S.-Japan Cooperative Medical Science Program. Research results are presented at a U.S.-Japan joint meeting each year. In FY 1984, the NIAID will obligate an estimated $1.5 million for research on TB. Research projects underway deal with the problem of drug resistance, the pathogenesis of virulent human tubercle bacilli in attacking the defense mechanisms of the human lung, and on host immune responses to the invading TB bacilli. Studies have also continued on the duration and mechanism of protection induced by the avirulent (nonpathogenic) BCG (Bacille Calmette-Guerin) vaccine strain of the tuberculosis organism.

## FOREIGN RESEARCHERS

Question: What do people from tropical countries study or research while in the U.S., especially those on U.S. assistance, such as the Fogarty fellowship program? Are they working on questions of relevance to their countries' needs? Is this a consideration in the acceptance process?

Answer: Scientists from tropical countries conduct collaborative research in areas of biomedical research and health that are of mutual interest to the United States and other countries. The areas cover very basic research studies such as the molecular basis of retrovirus virulence or immunogenetic factors involved in susceptibility to malaria as well as more applied studies such as methods for blood preservation or risk assessment of environmental carcinogenesis.

Considerations for making fellowship awards include the quality of the proposed research, the qualifications of the foreign scientists, the importance of the collaborative research opportunity to both the investigator and the U.S. host, the importance of the proposed research to health problems of global concern, and the prevention of disease or maintenance of health worldwide.

Some International Research Fellows supported by the Fogarty International Center perform research of direct relevance to their countries' needs. For example, a scientist from India in collaboration with a U.S. scientist is studying the control of ticks and tick-borne diseases; a scientist from Sudan in collaboration with a U.S. scientist is studying schistosomiasis in animals. In all instances, however, research advances in one scientific area have applicability to other areas. Further, with worldwide mobility of populations, knowledge of cause, treatment, and prevention of diseases endemic to one geographic area will help address the disease worldwide.

Question: What are the trends in training and other support of visiting foreign researchers in the U.S.?

Answer: Visiting foreign researchers in the United States are working in all areas of biomedical and behavioral science with current primary concentration in molecular biology and immunology. NIH currently has scientific agreements with over 60 countries. Through such collaborative activities, we have been able to both obtain advanced knowledge from other industrialized countries as well as improve the science base and resources of developing countries. These trends have been stable in recent years.

## GORGAS MEMORIAL INSTITUTE

Question: In January, the Committee received a progress report from the Gorgas Memorial Institute (GMI), as was required in our report last fall. One of the actions GMI proposes is to create a full-time position at GMI for a Chief Executive Officer. NIH (by Fogarty, NIAID, and to some extent NCI) has had experience in working with Gorgas and contracting with them. Would strengthening GMI (i.e., the Washington-based component) be beneficial to your relationships with Gorgas?

Answer: The strengthening of the GMI through creation of a full-time Chief Executive Officer should be beneficial in the NIH's relationship with the Gorgas Memorial Laboratory. A full-time Chief Executive Officer would give the GMI enhanced capability to serve certain mutual objectives; e.g., seeking an expanded base of financial support through contributions of other countries or organizations and aggressive pursuit of project grants, contracts, and other forms of collaborative scientific relationships.

Question: More specifically, based on past experience: In what general ways does GMI get involved in GML functions?

Answer: It is our understanding that the Executive Committee and President of GMI review and approve principal projects and financial actions of the GMI, including project grants and contracts. They negotiate with United States and other non-Panamanian organizations on collaborative scientific relationships for GML. They are the focal point for personnel actions for scientific and other principal GML staff, including recruitment, hiring, and promotions. They hold and disburse funds as are required for operation of the GML.

Question: What is GMI's involvement in the approval process for clinical protocols, either internally generated at GML or from the outside, e.g., contract studies? What is the breakdown of time for each step in the process? How does that relate to the efficiency of the work conducted? How does the GMI approval process relate to the local (Panamanian) approval process?

Answer: We understand that GMI's approval is required on all clinical protocols and other research projects to be undertaken at GML that involve external funding, resources, or a collaborative relationship. Once a project has been developed at the GML, the approval process by GMI is relatively brief--normally not more than a month. When an external funding source is involved, additional time may be required for that organization to complete its competitive review and award process. In the review by a contracting organization, all assurances for the conduct of clinical studies must meet their requirements. The GML/GMI part of the process is quite efficient because of the smaller size of the organization, but the process is otherwise similar to that of larger research institutions and universities. A standard Panamanian approval process is not required, but approval of the Ministry of Health or other appropriate Panamanian agency is obtained when a project involves Panamanian research subjects.

Question: In general, how does GMI facilitate clinical studies, particularly those done for U.S. government or private bodies?

Answer: GMI facilitates clinical studies done for U.S. government agencies or other organizations by being the focal point for the negotiation of such studies. Personal contacts with most U.S. agencies are made much easier because of the physical location of the GMI in Washington, D.C.

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## Questions Submitted by Senator William Proxmire

### GRANTS FUNDED FROM TWO SOURCES

Question: Dr. Wyngaarden, a few months ago the staff asked for a copy of a grant award statement for a project that was listed in the Blue Sheet. They were notified that the grant had been withdrawn because the investigator had received funding from the National Science Foundation for the project. Don't you have a mechanism in place that allows you to determine if a research grant application is being considered by another Federal agency before you make an award?

Answer: The NIH maintains both formal and informal mechanisms to track grant applications that investigators submit to one or more other Government agencies and to non-Government funding organizations. PHS Form 398 (utilized by applicants for requests for research support) requires that an applicant list, for himself and for all professional staff who will be supported on the grant, three categories of information related to other support: active support; applications pending review and/or funding; and applications planned or being prepared for submission. This information must include sufficient detail to enable program staff to track applications that the investigator has submitted to other agencies if potential overlap exists. As a consequence, dual funding of the investigator for the same type of work is highly unlikely to occur.

A number of informal approaches to this issue also exist. One such example is a project initiated by the National Institute of General Medical Sciences (NIGMS). Because of its mandate to support basic research, which does not fall directly under the aegis of one or more of the categorical Institutes of NIH, NIGMS funds many projects in categories of basic research similar to those funded by the National Science Foundation (NSF). As a consequence, NIGMS and NSF have in operation a system that ensures frequent contact between program staff of both agencies, utilizing mutual access of computerized information and direct personal contact among science administrators of both agencies. Other program staff of the NIH have access to the same systems and, in most cases, double check with the investigator about other current support prior to making an award.

Examples of other informal approaches to prevent duplication of research effort include contact between staff of the NIH and staff of the American Heart Association, the American Cancer Society, and other similar outside organizations. A number of these non-Governmental organizations support research that is closely akin to that which NIH funds.

Members of NIH study sections also assist in identifying cases where possible overlap of support may occur.

## GRANT COST GROWTH

Question: Between FY 1983 and FY 1984, the estimated average cost for a noncompeting research grant is expected to increase from $124,500 to $138,200 -- about 11 percent. The average cost for a competing grant is projected to rise from $119,500 to $137,200 -- almost 15 percent. How do you account for these sharp cost increases in the face of an estimated 4.4 percent increase in the Consumer Price Index?

Answer: First of all, it should be noted that the 1983 average costs reflect downward negotiations of 3 percent from full noncompeting costs and 9 percent from full new and competing costs. In 1984, Congress provided sufficient funds to support research project grants at close to full costs with reductions of approximately 1 percent in noncompeting and approximately 3 percent in new and competing grants. Thus, average cost comparisons between the 2 years are distorted by the different policies in effect. A more meaningful comparison would be between full costs in the 2 years: for noncompeting grants the average full cost increased by 9 percent; for new and competing grants the average full cost increased by 8 percent. Many factors contribute to the average cost growth besides inflation. These include: (1) changes in the mix of the type of grants supported; (2) changes in the technology used in research; and (3) the conduct of increasingly sophisticated research.

Question: Given these sharp increases in the cost of doing biomedical research in FY 1984, isn't it unrealistic to assume an average increase of 5 percent in biomedical research costs in FY 1985 when the administration has estimated an acceleration in the cost-of-living increase?

Answer: Considering the current economic situation and the efforts to reduce inflation, the decision to provide a 5-percent average cost increase was considered reasonable.

## RESEARCH TRAINING

Question: Dr. Wyngaarden, an article that appeared in the December 21, 1983, issue of The Blue Sheet pointed out that between 1968 and 1972, 71 percent of physicians who applied for NIH grants had previously received some NIH-supported research training but that only 64 percent of grant applicants who were actually awarded funding had received past support as NIH trainees.

Although this data was cited to show that postdoctoral research training produces successful investigators, it could also be interpreted as meaning that those who received NIH-supported research training were less likely to be successful in competing for research grants than those who did not receive such training, or does the article refer to two distinct groups?

Answer: The figures cited in The Blue Sheet were extrapolated from a study designed to show the fraction of postdoctoral research training supported by NIH, not whether research training produced successful investigators. The study pointed out that, of those faculty members with M.D. degrees hired between 1968 and 1972 and who applied for NIH research grants, 71 percent had received NIH research training. Of those faculty members who received NIH research grants, 64 percent had received NIH research training. Thus, the data do not support an interpretation that NIH-training-supported investigators are less successful in grant competition than other groups.

## SUPPORT FOR HEALTH R&D

Question: Dr. Wyngaarden, your NIH data book for 1983 indicates that over the last ten years or so the proportion of national health research and development funded by the Institutes stayed more or less constant, industry support increased from 26 percent of the total to 39 percent of the total and other Federal aid fell from 25 percent to 16 percent. Why has other Federal aid fallen so sharply in the last 10 years?

Answer: The relative decline of non-NIH Federal support in the national health R&D picture is a function of substantial increases in industry funding and a decline in support for health R&D by agencies other than NIH.

Industry health R&D funding, particularly moneys spent by the pharmaceutical companies, outstripped Federal support during the past decade. Industry funding rose more than 4-fold between 1972 and 1983, or at an average annual rate of 14 percent--far outpacing the inflation rate. Federal support from all agencies including NIH, on the other hand, increased 2.5-fold, or at an average annual rate of 8.8 percent.

Only NIH has experienced a substantial increase in health R&D funding among the various agencies supporting such R&D. While agencies other than NIH have invested more current dollars each year than the previous year, the growth rates have been less than either industry or NIH growth rates.

The result of both factors combined is a considerable relative decline for the non-NIH Federal agencies for recent years.

It should of course be noted that the R&D supported by industry and the Federal government are not substitutes for one another. Federal support, particularly that provided by NIH, represents most of the basic science underpinnings, whereas industry R&D is directed more toward the applied research and development end of the R&D spectrum. Good figures are not available, but rough estimates indicate that more than 40 percent of Federal health R&D represents basic research, whereas for industry only 9 percent lies in that category.

### NURSING RESEARCH

Question: What is the projected cost of establishing a National Institute of Nursing Research at NIH?

Answer: We have no estimated cost for establishing such an institute at this time. In part this is due to the fact that there is no established or existing program of this nature at NIH to serve as a model for projecting these costs, unlike the case of the proposed Arthritis Institute.

## NATIONAL CANCER INSTITUTE

## STATEMENT OF DR. VINCENT T. DeVITA, JR., DIRECTOR

ACCOMPANIED BY:
- DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
- JOHN P. HARTINGER, FINANCIAL MANAGER, NATIONAL CANCER INSTITUTE
- ANTHONY ITTEILIG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

### BUDGET REQUEST

Senator WEICKER. Now we move to other branches of the Institutes of Health. First, we'll hear from the National Cancer Institute which has the responsibility for conducting the so-called war on cancer.

NCI appears before the subcommittee not long after newly updated figures show that 48 percent of cancer patients have 5-year survival rates compared to only 20 percent a decade ago. The Cancer Institute receives a major share of the NIH budget.

The request for fiscal 1985 is $1.1 billion, or about $24 million more than the appropriation for fiscal year 1984. The lead witness is our good friend, Dr. DeVita, Director of the Institute.

Dr. DEVITA. Thank you, Senator. On my left we have Mr. John Hartinger, the Chief of our Financial Management Branch and Chief Budget Officer. I believe you've met everybody else.

### PREPARED STATEMENT

Senator WEICKER. Before we proceed, we will insert your statement in the record.

[The statement follows:]

## STATEMENT OF DR. VINCENT T. DEVITA, JR.

I appreciate the opportunity to present the progress and accomplishments of the National Cancer Program (NCP). Because of the payoff from cancer research, the National Cancer Institute (NCI) this year has set a target we believe achievable for the year 2000--to reduce the Nation's cancer mortality by 50 percent of what it is today.

In human terms, this would mean saving over 200,000 lives a year. We feel confident that half of this goal can be achieved by applying new knowledge in diagnosis and prevention and the other half from improvements in the development and dissemination of treatment information.

Our goal is realistically based on the success of past, current and future research. To meet it requires new approaches in applying the research findings generated in our laboratories and clinics--the underpinning of our entire program. We are taking the following major steps toward achieving our goal:

- We are recommending dietary changes that we believe will reduce incidence and mortality from several major cancers. Some 35 percent of cancer is influenced in some way by what we eat. Consider colon cancer: studies show a continuous theme--a low risk of colon cancer in populations with high-fiber diets. An acceptable and easily achievable increase of fiber in our diet over the next 5 years can reduce colon cancer mortality by 30 percent by the year 2000. This would prevent 20,000 deaths annually from colon cancer. Currently, Americans eat about 10-15 grams of fiber per day. We need to double that amount. To help people make appropriate food selections, we are preparing booklets with information on the fiber content of common foods. These pocket-size books will be easy to attach to a grocery list and will be available to the public as part of our new prevention awareness campaign.

- Smoking now causes 30 percent of cancer deaths. But the tide of public opinion has turned against cigarette smoking. We believe we can reduce smoking to 50 percent of current levels by the year 1990. This would give us a decade of reduced cancer risk in former smokers, resulting in as many as 75,000 fewer deaths a year from smoking-related cancers by the year 2000. We feel we are well on our way for we now have the lowest per capita consumption of cigarettes in the past 25 years. Nonsmoking airlines already attract smokers who want to abstain. Pilot self-help and school programs to stop smoking are working. NCI has efforts under way to enlist physicians and dentists, the media, schools, and special target populations--blacks, Hispanics and blue collar workers--to modify smoking behavior and save lives. We must, however, find new ways to make smoking cessation less painful--maybe even fun.

- With regard to our goals in treatment, noting geographic variations in patient survival in the U.S.A. has led us to believe we can raise the current national survival rate by at least 10-15 percent, or more than 40,000 lives each year, if every patient receives today's state-of-the-art treatment.

In the past decade, the NCP has supported and trained a cadre of cancer specialists that did not previously exist in sufficient numbers. These highly trained individuals practice in a variety of settings, from comprehensive cancer centers to private practice settings in small communities. We have effectively networked the country with cancer centers, cooperative groups of clinical researchers, and with a new program, the Community Clinical Oncology Program (CCOP). This program links community physicians with NCI clinical research programs, so that more cancer patients can participate in clinical trials in their own communities. NCI has funded 62 CCOPs affiliated with over 200 hospitals in 34 states.

This year, PDQ, our new physicians' data query system, completes the final link in a chain of information on advances in cancer treatment that stretches from laboratory and clinical research to the practicing physician. PDQ is a computerized database available to physicians nationwide. Geographically matrixed, it offers the latest information on state-of-the-art treatments and ongoing clinical trials for each type and stage of cancer. The information is easily accessible via the National Library of Medicine which has worked closely with NCI, and through personal computers. The rapid transfer of cancer technology is a reality.

In addition, 500,000 patients are diagnosed each year with cancer that does not appear to have spread beyond the primary site. In the past, these patients were treated for "local," not systemic disease, and 200,000 of them relapsed. By using currently available radiation therapy and chemotherapy following surgery, 70,000 lives could be saved each year. In the future, with application of biological therapy such as monoclonal antibodies and other new treatments, these figures could increase even more dramatically.

As well as setting goals, we must monitor our progress. NCI's Surveillance, Epidemiology, and End Results (SEER) Program annually monitors cancer incidence, mortality and survival in 12 percent of our population. Most recent SEER data show that 48 percent of cancer patients diagnosed between 1973 and 1980 survived their disease 5 years or more. The vast majority of these patients can be considered cured. Although data for 1983 are not in yet, we firmly believe we have now passed the 50 percent curable mark for cancer. For a number of major types of cancer, more than two-thirds of all patients are curable, a fact still not widely appreciated.

## New Leads in the Research Laboratory

Support for basic research has been and continues to be the first priority of the National Cancer Program, because basic research is the source of all our successes. The resources provided by the National Cancer Act of 1971 provided the stimulus for a generation of creative science, reflected in the current biological revolution. From 1972 to 1980, NCI was essentially the sole source and still remains the main source of the enzyme reverse transcriptase, a critical tool for recombinant DNA work which has led to today's burgeoning field of biotechnology. The discovery of restriction enzymes--nature's scalpels for cutting DNA--and development of recombinant DNA and monoclonal antibody technologies in the 1970s have created whole new vistas for basic research and the applications of basic research in cancer.

The resources which supported the cancer virus studies over the past decade brought the discovery of oncogenes--small pieces of genetic material in the heart of your cells and mine, intimately involved with cancer development. We have made a quantum leap in understanding what cancer means. Cancer had been in a black box that research has now opened and scientists are busy studying the gears of its machinery. Research now indicates that oncogenes are a common point of vulnerability, vital switches involved in growth control within cells where chemicals, radiation or perhaps viruses activate the cancer process. We now have the potential to interfere with that process as never before.

So far, about 24 oncogenes have been discovered and "mapped" to their location on our chromosomes. Oncogenes appear to have been part of us for a long time. Because they were conserved through evolution, it seems they must carry out some necessary function in the cell.

Great excitement also surrounds research to identify the products made by oncogenes. Developing ways to destroy or block such products could have unparalleled impact on cancer prevention, diagnosis and treatment. Already such oncogene products have been identified and monoclonal antibodies that react to the gene and gene products are available for further study. Recently, NCI scientists have developed a monoclonal antibody that can specifically identify and target an abnormal protein product of a cancer oncogene. This antibody in laboratory tests is able to home in on the exact part of the protein structure that has changed.

## Prevention

Cancer prevention is a high priority and a critical mandate of the National Cancer Program. We believe our success in basic prevention research now allows us to be less cautious about recommending steps that we can take to prevent cancer, some of which I mentioned earlier. We have begun a major prevention awareness program to help reach our goals established for the year 2000 and this includes dietary guidelines and modifications. In addition to focusing on diet, we have begun studies with so-called chemopreventive agents. These agents include micronutrients like vitamin A; its derivatives the retinoids, and its precursor beta-carotene; vitamins C and E; and selenium. All have been found to stop or reverse the cancer process in laboratory and animal studies. Building on basic research in prevention over the past 10 years, we are now studying such agents in 20 clinical studies in efforts to prevent various cancers. We should be able to determine by 1990 whether certain types of cancer can be prevented by adding chemopreventive agents to the diet.

In another area called "biochemical epidemiology," we are now able to identify individuals who are at high risk of cancer due to occupation, lifestyle, or inherited factors. Sensitive laboratory methods now can determine if a carcinogen (a cancer-causing agent) has been incorporated into a person's tissues and become bound to the DNA of the cells. The DNA with a carcinogen attached is called a DNA-adduct. The laboratory methods can also predict an individual's capacity for repair of the DNA with which a cancer-causing agent has reacted. DNA is believed to be the point of attack for most carcinogens that begin the cancer process, and such repair could stop the process. Meantime, in animal studies, the amount of DNA adducts formed by a carcinogen is correlated with the dose to which the animal was exposed. This research has important implications for extrapolation to humans in developing risk assessment for various agents.

## Detection and Treatment

Part of our progress against cancer is due to earlier, more accurate diagnosis as well as better treatment. For example, sensitive new gene markers identify lymphomas of uncertain cell type. Such ways to identify specific types of cancer are helping physicians to make better treatment decisions based on correct diagnosis. Also, improved means of "staging" patients--determining more precisely the extent of their disease--are leading to better choices of therapy and better survival.

Utilizing the three main forms of cancer treatment, surgery, radiation therapy and chemotherapy, has led to continuing increases in cancer patient survival. We can now select the primary type of treatment that is most appropriate, guided by the availability and effectiveness of the other treatment modalities. This gives cancer patients their best chance at the time of diagnosis for treatment more tailored to their case. Some surgical procedures, for example, are moving away from more extensive approaches as other ways to complement surgery with chemotherapy and radiation therapy have become available. We are also improving the quality of life of cancer patients during and after treatment. Less radical surgery is being used for a number of patients with breast cancer, sarcomas of the limbs, and prostate cancer. For patients with prostate cancer, we are also studying new, promising hormonal therapy, using the hormone LHRH.

In chemotherapy, we continue to develop new drugs that are more targeted and effective, but less toxic for patients. Also, scientists have discovered important new information that is providing us with tools soon to be used in designing treatment. They have found: 1) the way certain cancer cells "intuitively" become resistant to drugs, leading to treatment failure, and 2) the unique way certain cancer cells become invasive and spread, and therefore develop sites of disease distant to the original site, often in vital organs, which is the main cause of cancer deaths.

Meantime, new tools like laser surgery are being studied for treating cancer, and a newcomer or "fourth modality" of cancer treatment--biologicals and biological response modifiers--is coming into its own. Many of these natural products are under study in our clinical trials programs. In biologicals, we are learning more and more how to make components of the immune system work for us. Monoclonal antibodies are designed specifically to target cancer cells. They promise to be effective for the diagnosis and treatment of cancer, either when used alone, or armed with radioisotopes or toxins. While our projections for reducing cancer mortality by the year 2000 do not include the help we may get from such exciting techniques now on the horizon, this year will result in the broadest testing of monoclonal antibodies in our history and give us firm evidence of their applicability in the future.

Mr. Chairman, the request for the National Cancer Institute for Fiscal Year 1985 totals $1,101,069,000. This is an increase of $23,790,000 over the comparable 1984 estimate. This concludes my statement. I am prepared to answer questions and to supply additional information for the record.

## BIOGRAPHY OF DR. VINCENT T. DEVITA, JR.

Date & Place of Birth: March 7, 1935; Bronx, New York

Education: 1957 - B.S. (Chemistry) College of William and Mary, Williamsburg, Virginia

1961 - M.D. (with distinction) George Washington University School of Medicine, Washington, D.C.

Positions held:

1961-62: Internship, University of Michigan Medical Center, Ann Arbor, Michigan

1962-63: Residency in Medicine, George Washington University Medical Service, District of Columbia General Hospital, Washington, D.C.

1963-65: Clinical Associate, Laboratory of Chemical Pharmacology, National Cancer Institute, Bethesda, Maryland

1965-66: Senior Residency in Medicine, Yale-New Haven Medical Center, New Haven, Connecticut

1966-68: Senior Investigator, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1968-71: Head, Solid Tumor Service, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1971-74: Chief, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1974-80: Director, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1975- : Clinical Director, National Cancer Institute, National Institutes of Health, Bethesda, Maryland

1980- : Appointed by the President, Director, National Cancer Institute, National Cancer Program, National Institutes of Health, Bethesda, Maryland

Academic Appointments:

Associate Professor of Medicine, George Washington University School of Medicine, Washington, D.C., 1971-75.

Professor of Medicine, George Washington University School of Medicine, Washington, D.C., 1975-

## Editorial Boards:

Associate Editor, Journal of the National Cancer Institute, Bethesda, Maryland, 1968-74
Scientific Editor, Cancer Chemotherapy Reports, National Cancer Institute, 1970-74
Advisory Editor, Journal of Radiation Oncology, Biology, and Physics, 1975-
Associate Editor, Editorial Advisory Board, Cancer Research, 1977-81
Member, Board of Medical/Scientific Consultants, Cancer Nursing, 1978-80
Member, Board of Scientific Council, Cancer Chemotherapy and Pharmacology, 1977-
Associate Editor, Cancer Clinical Trials, 1977-
Associate Editor, Cancer Investigation, 1983-
Member, Editorial Board, American Federation of Clinical Oncologic Societies, 1977-78
Member, Editorial Board, American College of Physicians (A.C.P.) Audio Cassette Program, 1979-80
Member, Editorial Board, Seminars in Oncology, 1979-84
Associate Editor, The American Journal of Medicine, 1978-81
Member, Editorial Advisory Board, Breast Cancer Research and Treatment, 1980-
Member, Editorial Board, Your Patient & Cancer, 1980-
Member, Editorial Board, Gynecologic Oncology, 1981-
Member, Editorial Board, Hematological Oncology, 1981-
Member, Editorial Advisory Board, Physicians' Drug Alert, 1982-
Member, Editorial Board, Journal of Clinical Oncology, 1982-
Member, Editorial Board, Cable Health Network, 1983-

## Committees and Other Offices:

Councilman, Assembly of Scientists of the National Cancer Institute, National Institutes of Health, 1968-70
Chairman, Program Committee, American Society of Clinical Oncology, 1972
Clinical Research Committee, National Cancer Institute
Board of Directors, America Society of Clinical Oncology, 1973-76
American College of Surgeons' Commission on Cancer, Committee on Patient Care and Research, 1975-
Advisory Committee on Clinical Investigations II - Chemotherapy and Hematology, American Cancer Society, 1975-76
Publications Committee, American Society of Hematology, 1975-
WHO Expert Advisory Panel member, 1976-
Board of Directors, American Association for Cancer Research,1976-79
Lasker Award Jury, 1976-
President, American Society of Clinical Oncology, 1977-78
Chairman, Treatment Committee of the French-American Agreement, 1976-
Chairman, Special Membership Committee, American Association for Cancer Research, 1978-79
Member, Panel of Consultants on Clinical Oncology, International Union Against Cancer, 1979-82

## Specialty Board Certification:

Diplomate of the National Board of Medical Examiners, 1961
Diplomate of the American Board of Internal Medicine, 1968

Diplomate in the Subspecialty of Hematology, American Board of Internal Medicine, 1972
Diplomate in the Subspecialty of Medical Oncology, American Board of Internal Medicine, 1973
Recertification, American Board of Internal Medicine, 1974

Professional Societies:

Fellow, American College of Physicians
American Medical Association
American Society of Hematology
American Society of Clinical Oncology
American Association for Cancer Research
American Federal for Clinical Research
American Society for Clinical Investigation, elected May, 1972
Society of Surgical Oncology (James Ewing Society) 1976-79

Honors and Awards:

Alpha Omega Alpha Medical Honor Society
Smith-Reed-Russell Medical Honor Society
Tobacco Research Industry Fellowship, Mount Desert Island Biological Laboratory, Bar Harbor, Maine, 1959
"Oren del Sol en el Grando de Official," awarded by the Government of Peru, 1970
Visiting Professor of Medicine, Stanford University School of Medicine, July, 1972
Albert and Mary Lasker Medical Research Award, November, 1972
First Annual Clowes Lecture Roswell Park Memorial Institute, October, 1973
DHEW Superior Service Award, 1975
Esther Langer Award, June, 1976
Alumni Medallion, College of William and Mary, October, 1976
Jeffrey Gottlieb Award, November, 1976
Karnofsky Prize, 1979
Griffuel Prize, Association for the Development of Research on Cancer, Paris, December, 1980
James Ewing Award, The Society of Surgical Oncology (The James Ewing Society) Marco Island, Florida, April, 1982
Honorary Doctor of Science Degree, The College of William and Mary, Williamsburg, Virginia, May, 1982
Alumni Achievement Award, The George Washington University, February, 1983
Honorary membership, Society of Gynecologic Oncology, January, 1983
Honorary membership, Japanese Cancer Society, February, 1983
Honorary fellow, American College of Radiology, April, 1983
Award for Outstanding Support of Biomedical Science, Memorial Sloan Kettering Cancer Center, May, 1983
PHS Distinguished Service Medal, May, 1983
Honorary Doctor of Science Degree, Ohio State University, June, 1983

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SUMMARY STATEMENT

Dr. DEVITA. I'd just like to highlight a few points that were in my opening statement in reference to the Cancer Program.

First, we handed out to the committee a functional flow diagram of the Institute which emphasizes two main features of the Cancer Act. One, that it was to supply funds for the support of basic research that we have already discussed this morning; and the other was to give us the tools to apply the results of basic research.

We have just recently completed what we consider the network for the application of the results of basic research. For your interest we have a map which illustrates this network; about 150 million dollars' worth of resources including cancer centers, clinical trials, and community programs to help us apply the results of the basic research are consumed annually by this network.

Let me first make a few comments about basic research. Dr. Wyngaarden has already alluded to the fact, in his opening comments, that basic research has changed dramatically in the last few years. We can look at cancer as a black box that was something we could turn and shape and weigh before. Now we have pulled the lid off the black box and we are now looking inside watching the gears go around.

I am referring specifically to things like discovery of oncogenes and their implications; the discovery of the human T cell lymphoma virus that Dr. Wyngaarden alluded to by Dr. Gallo at the Cancer Institute; and the discovery and use of monoclonal antibodies produced by hybridomas. All of these discoveries are reaching the point of clinical application. Newer discoveries like fragile sites on chromosomes may soon allow us to predict people who might be at risk of getting cancer as a result of exposure to a carcinogen.

On the application side, applying the results of research through that network has resulted in reduced national mortality and improvement in survival. This has allowed us to make some projections for the year 2000. Our goals are to reduce the current rate of mortality from cancer by about another 50 percent by the year 2000.

We think these are achievable goals. Using today's figures, that would mean about 200,000 lives a year saved.

Half would be accomplished through dissemination of state-of-the-art treatment and the other half through prevention. In addition to the usual emphasis on cigarette smoking and its impact on cancer incidence and mortality, we have a new program which we've just launched, a Prevention Awareness Program, to support cancer prevention through dietary intervention. The centerpiece of that program is, in fact, the doubling of the fiber content of the American diet by the year 1990 in order to reduce colon cancer incidence by about 30 percent by the year 2000. We believe that all the things Senator Andrews said, including the effect of some of the types of bran and cholesterol levels in the blood, are in fact true. We have taken steps to inform the American public about this, and it is part of our projections and our goals.

Our budget for 1985 is $1,101,069,000, an increase of $23,790,000. I will stop at that point and answer questions.

Senator WEICKER. I know this always comes up on the floor of the Senate, but I really haven't had time to pay attention to the exact dollar figure. What do we supply in terms of subsidy for tobacco?

Dr. DEVITA. I'm not really sure.

Senator WEICKER. Does anybody have that dollar figure?

Dr. DEVITA. I don't.

Senator WEICKER. I'd appreciate it if staff would produce that dollar figure. I'd like to see how that matches up to the dollar figure for this particular Institute.

I might add, this series of questions I'm going to ask goes to every one of the institutes. To what extent will your new and continuation grants be funded below full cost levels, and what important research will be delayed or eliminated as a result?

Dr. DEVITA. We don't have any funding plan per se for the competing renewals and the new grants, but in the process of normal negotiation we'll be reducing our new grants approximately 3.8 percent and our competing renewal grants by about 2.9 percent.

I'm not sure this will have a significant impact on the research that's being conducted in those particular grants. In other words, this is a process of negotiating we normally go through even in the best years.

Usually the reduction is about 2.7 percent. It's a little bit higher this year.

Senator WEICKER. With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in fiscal year 1985 that you had in fiscal year 1984?

Dr. DEVITA. We are keeping the numbers roughly the same. There's been a little bit of a turnover that does affect the geographic distribution. Two centers have decided not to come in for renewal and we have funded one new center in Nebraska. The centers that are not coming in for core grants are either on the east coast, in one case in a city where there is a large center, and in the other case it's on the west coast, where the institution is part of one of our consortium centers. The newly established center is in Nebraska, an area that we didn't have a center before. So the offsetting, at least geographically, is not too bad at this point.

Senator WEICKER. The overall NIH budget proposes a cutback in research training. What is the impact on your Institute?

Dr. DEVITA. We are funding 1,181 FTE's in 1985 compared to 1,280 in 1984. It's a slight reduction in our numbers of trainees. We do have to be careful that we don't diminish the stability of basic research to the extent that young scientists are not interested in coming into it because of the absence of training slots.

Senator WEICKER. How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Dr. DeVita. I believe we're talking about $1.147 billion possibly, as our total request in order to maintain the same level of activity in 1985 as in 1984.

Senator Weicker. The budget proposes a staff cut of 588 for all of NIH. What is your share of the proposed reduction?

Dr. DeVita. Ninety-five.

Senator Weicker. And where are you going to take them from?

Dr. DeVita. We're hoping to take all of them from the other-than full-time category about 80 of which will come from the Intramural Program. The remainder will come from our cancer control programs and administrative staff. We may have to reduce our summer program a good deal to absorb some as well.

Senator Weicker. What is your Institute's involvement with the matter of AIDS? Can you comment on that?

Dr. DeVita. When we began to look, with the rest of NIH, at the issue of AIDS—each Institute put their best foot forward. Our strength was in cancer viruses, the tumor viruses called retroviruses, RNA tumor viruses. We organized a task force that emphasized research in this area.

Dr. Peter Fischinger, my associate director, is the coordinator of this effort.

Dr. Robert Gallo, who is the discoverer of the first human retrovirus known to be associated with a cancer, was made the scientific director of this task force and has made, we believe, major contributions because the human T cell lymphoma virus seems to be associated with AIDS. We are anxiously pursuing this area. So NCI has played a major role in the AIDS research effort. About $15 million is planned in 1985 on AIDS research, and a little more than $12 million in 1984.

Back in 1982 we only had $2½ million. So support has grown rapidly.

Senator Weicker. There seems to be a brewing controversy over whether to count special experts in NIH personnel ceilings. It is my understanding that these special experts are scientists who bring needed expertise to the work of NIH.

What is the story here? How does the present policy of counting these special experts in your personnel ceilings differ from what Congress originally said you should do?

Dr. DeVita. The original intent of the Congress, with respect to experts, was that they were to be ceiling exempt. This was stated in the report language. Some years ago, when the Secretary was queried on this issue, that intent was acknowledged.

In 1983, March, we were told that experts would now be included in this personnel ceiling. Since that time they have been included. Some allocation has been made to the NIH for coverage of not only NCI but NIH experts.

The major drawback is that experts are temporary positions. We use them that way. We go out to get special expertise at the time when we need it.

Being temporary personnel with appointments that average 4 years, there are enough uncertainties without having the uncertainty of not knowing what will happen to them if future cuts occur.

It's taken away a little bit of our recruiting edge for experts from the time of having them ceiling exempt.

Mr. ITTEILAG. Could I comment, Senator?

Senator WEICKER. Yes, indeed.

Mr. ITTEILAG. The heart of the problem, with respect to whether these experts should be counted in the ceiling or not, is that the congressional direction was included in report language only and it was not in the law. Therefore, the distinction that was made on a Government-wide basis, was simply that if the Congress, through legislative action, provides that certain categories of personnel are to be exempt then they will be ceiling exempt. But other than through this device, rather than through another device from the Congress, such as correspondence or report language or any other nonlegislative mechanism, it is not considered to be sufficient in order to provide a ceiling exemption. This is not a matter of just NIH or just the Department, but rather this policy is Government-wide.

Senator WEICKER. Mr. Itteilag, you are telling me the obvious; that is, that the administration has no intention of paying any attention to report language. Believe me, we've all learned that over the last several years.

Mr. ITTEILAG. Senator, I don't think it's entirely fair to say that——

Senator WEICKER. Well, I think it's entirely true. I think that's entirely true. The difficulty I have with it is that I think I would thoroughly agree with you.

Report language does not have the same force of law, but it's usually a matter that the executive and the legislative branches manage to work out. In this particular instance, no attention has been paid; at least in every instance that I've had a chance to observe.

What you're telling me is unless we change the law here, you know, this matter of experts is one that will continue by virtue of the rulings of OMB; which is that they will be included in the personnel ceilings.

Mr. ITTEILAG. I think, in this one instance, that's correct; but if you look at it on a Government-wide basis there would literally be thousands and thousands of personnel who would not be counted in personnel ceilings because the Congress, through one device or another other than legislation, has said, "Don't count these people."

So while this particular situation is unique for the Department in terms of a realistic count of Federal employment, to exclude any class of personnel from ceiling any time the Congress indicates such a desire, other than through legislation, would greatly distort the number of people working for the Federal Government.

Senator WEICKER. Well, the alternative, of course, is to up the funding. We can handle it in that fashion.

I gather this affects, then, the hiring of others you would like to have permanently on your staff. Would that be correct?

Dr. DeVita. When cuts are made they are made in all groups now. For example, the experts are in the other-than full-time category, so the potential of not filling all our expert positions as a result of a position cut is there, where, in the past, it might not have been.

The major issue is the point I made earlier. I don't disagree with Mr. Itteilag in terms of his interpretation at all.

When you're trying to recruit somebody from a distance for a temporary appointment they say if they're going to move their family for 4 years and it's a temporary appointment, it might become even more temporary if NCI loses control over it. It has hurt us on the recruiting side.

This was an unforeseen benefit of the positions being ceiling exempt in the first place; it provided a little bit of stability. That's very important.

Senator Weicker. I have other questions, Dr. DeVita, for response to the record. Is there something further that you want to expand on in terms of this chart that you showed me here?

Dr. DeVita. No; it's just to illustrate the network we have in place, Senator. We believe all the components are complete at the present time. There are some areas of the country, however, that don't have many dots. They tend to be low population density areas. The idea is to provide resources out there in the country for basic research, and its application. This network is the main instrument to get that mortality figure down by 50 percent by the year 2000.

We do feel confident that these are not overly ambitious goals. In fact, if we didn't do anything special at all and project the lines the way they are going now, we are almost a third of the way to those goals.

It is a very pleasing kind of thing for us. I just wanted to show you how the map looks.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator Weicker. Thank you very much. There will be other questions for response to the record.

Dr. DeVita. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutback in training, etc.

To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: The budget process is a long and arduous one involving interplay between many people at various agencies, including the National Institutes of Health, the Public Health Service, Department of Health and Human Services, and Office of Management and Budget. We have varying degrees of involvement during the months required to formulate the budget. Here at the NIH level, all of the Institute Directors are given an opportunity to discuss budget policy implications. We, as with all of the other BIDs, received a final 1985 budget figure within which allocations were made to adhere to established budget policy. In addition, the philosophy behind the 1985 budget is one that NCI supports, that is, we recognize the importance of stabilizing the research project grant pool.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: The President's budget provides a 2 percent increase over the 1984 level and will permit the Institute to fund its highest priority projects. While there is always the opportunity to accelerate the momentum inherent with biomedical research, I feel the request before you will permit us to maintain that momentum which has been developed over the past years.

### IMPROVED SURVIVAL RATES

Question: The Subcommittee is impressed with recent reports showing improved survival rates among cancer patients. The information we have shows that 48 percent of all patients diagnosed with cancer between 1973 and 1980 survived their disease five years.

What is the 48 percent an increase from?

Answer: Among cancer patients first diagnosed during the period 1973-1980, the five-year relative survival rate was 48 percent. This compares with a rate of 38 percent among those diagnosed during 1960-1963 and 42 percent among those diagnosed during 1970-1973.

Question: What accounts for this development -- and to what extent do five-year survival rates represent a cure?

Answer: The improvement in survival rates is accounted for by a combination of factors that varies for specific cancers. In most instances it is due to improved treatment or case management, in others, the improvement is due to earlier diagnosis, earlier treatment, and in many instances, therefore, better prognosis. To illustrate, with the widespread application of new treatment for testicular cancer since the mid-1970's, for example, that disease has become virtually completely curable. With more aggressive treatment of acute lymphocytic leukemia in children, which accounts for over 20 percent of cancers in children, the five-year survival rate has increased from 4 percent among children diagnosed during 1960-1963 to over 58 percent among those diagnosed during 1973-1980 and the survival rate is still increasing. The five-year relative survival rate measures the chance of surviving the effects of cancer after adjusting for deaths from other causes. Therefore for most cancer it is a good estimate of the curability of the disease.

Question: What cancers are involved in these improved survival rates?

Answer: Improved survival rates are evident for almost every cancer from the early 1960's to the late 1970's. Table 1 shows the five-year relative survival rates for specific cancers over three time periods -- 1960-1963, 1970-1973, and 1973-1980 for white patients. Table 2 shows comparable data for white children under 15 years of age. Data for black patients over this time period are not sufficiently comparable to permit assessment of changes.

TABLE 1

Five-Year Relative Survival Rates for Selected Sites for White Cancer Patients, Diagnosed During the Years

| | 1960-63[1] | 1970-73[1] | 1973-80[2] |
|---|---|---|---|
| Endometrium (corpus) | 73 | 81 | 88 |
| Breast (females) | 63 | 68 | 74 |
| Cervix | 58 | 64 | 68 |
| Bladder | 53 | 61 | 73 |
| Prostate | 50 | 63 | 68 |
| Colon | 43 | 49 | 51 |
| Rectum | 38 | 45 | 48 |
| Stomach | 11 | 13 | 14 |
| Lung | 8 | 10 | 12 |
| Pancreas | 1 | 2 | 3 |
| Leukemia | 14 | 22 | 32 |
| Non-Hodgkin's Lymphoma | 31 | 41 | 46 |
| Ovary | 32 | 36 | 37 |

| | 1960-63[1] | 1970-73[1] | 1973-80[2] |
|---|---|---|---|
| Kidney | 37 | 46 | 50 |
| Brain | 18 | 20 | 21 |
| Melanoma of the Skin | 60 | 68 | 79 |
| Hodgkin's Disease | 40 | 67 | 70 |
| Testicular Disease | 63 | 72 | 82 |
| Esophagus | 4 | 4 | 5 |

[1] Rates are based on data from a series of hospital registries and one population-based registry. They are summarized in Cancer Patient Survival Experience.

[2] Rates are from the SEER Program. They are based on data from population-based registries in Connecticut, New Mexico, Utah, Iowa, Hawaii, Atlanta, Detroit, Seattle-Puget Sound, and San Francisco-Oakland. They include patients diagnosed through 1980 and follow-up on all patients through 1981.

### TABLE 2

### Five-Year Relative Survival Rates for Selected Sites for White Children Under 15 Years of Age, Diagnosed During the Years

| | 1960-63[1] | 1970-73[1] | 1973-80[2] |
|---|---|---|---|
| Acute Lymphocytic Leukemia | 4 | 34 | 58 |
| Acute Granulocytic Leukemia | 3 | 5 | 22 |
| Wilms' Tumor | 33 | 70 | 75 |
| Brain and Central Nervous System | 35 | 45 | 53 |
| Neuroblastoma | 25 | 40 | 47 |
| Bone | 20 | 30 | 46 |
| Hodgkin's Disease | 52 | 90 | 84 |
| Non-Hodgkin's Lymphoma | 18 | 26 | 46 |

[1] Rates are based on data from a series of hospital registries on one population-based registry. They are summarized in Cancer Patient Survival Experience.

[2] Rates are from the SEER Program. They are based on data from population-based registries in Connecticut, New Mexico, Utah, Iowa, Hawaii, Atlanta, Detroit, Seattle-Puget Sound, and San Francisco-Oakland. They include patients diagnosed through 1980 and follow-up on all patients through 1981.

Question: In last year's hearing we discussed reports indicating that at least one noted cancer researcher was looking for "the end of cancer before this century is over." You said the individual in question was not given to making outlandish statements. A year later, do you feel that same way -- are we enroute to "the end of cancer before the century is over"?

Answer: The National Cancer Institute has set out to reduce cancer mortality by 50 percent from current levels by the year 2000. Reaching this goal would mean saving 200,000 additional lives a year. NCI is confident that half of this goal can be achieved by applying our current knowledge in cancer treatment nationwide. The other half will be by our efforts in prevention which largely consist of convincing people to change their lifestyle. To this end, NCI has launched a major Prevention Awareness Program with emphasis on diet and smoking as lead players in cancer.

It is believed that nearly 35 percent of cancer is influenced in some way by diet, and some basic changes could have a major impact on cancer incidence. In colon cancer, for example, studies have shown that a high fiber diet is associated with low colon cancer risk. An increased proportion of fiber content in the diet over the next five years could reduce colon cancer mortality by 30 percent by the year 2000, preventing 20,000 deaths annually. NCI is working vigorously to inform the public about the importance of dietary modification in preventing cancer. In addition to diet, NCI is also supporting studies on chemopreventive agents, substances which have been found to stop or reverse the malignant process in laboratory and animal studies. These agents include micronutrients like vitamin A, its derivatives, and its precursor beta-carotene, vitamins C and E and selenium.

The other major thrust of the prevention awareness efforts involves smoking, which causes 30 percent of cancers. NCI believes that smoking in this country can be reduced by 50 percent of current levels by the year 1990, resulting in as many as 75,000 fewer deaths a year by 2000. NCI is working to enlist physicians and dentists, the media, schools and special target populations to modify smoking behavior and save lives.

NCI's ability to confidently predict a 50 percent reduction in cancer by 2000 is largely the result of tremendous strides in knowledge acquired through research already completed. We believe the discoveries of today represent quantum leaps in understanding cancer. A good example of this is the discovery of oncogenes. These genes are found in all living cells, and seem to be a common point of vulnerability involved in growth control within cells where chemicals, radiation or perhaps viruses activate the cancer process. Identification of the products of these oncogenes offers great hope for developing ways to destroy or block such products, thus interfering with the occurrence or progression of cancer. Other examples of rapid advances include the development of monoclonal antibodies which can be specifically targeted and "armed" to seek out only the cancer cell; biochemical epidemiology, which allows scientists to identify individuals who are at high-risk of cancer by using laboratory methods to determine if a carcinogen has become bound to the DNA of the cell; the discovery of HTLV, the human T-cell leukemia/lymphoma virus; the realization that cancer cells seems to have an intuitive ability to develop a resistance to drugs in a predictable manner; and a far deeper understanding of the immune system. Since none of these discoveries and their possible applications have been factored into our goals for the year 2000, we may have been far too conservative in our estimates; the prediction of Dr. Lewis Thomas, a renowned and respected scientist, is not an outlandish one.

## AIDS

Question: The Subcommittee remains deeply concerned over the nation's ability to deal with Acquired Immune Deficiency Syndrome, otherwise known as AIDS. What progress is the Cancer Institute making in the effort to find the cause, or causes, of this terrible disease and devise effective treatment?

Answer: Recently, NCI has made a breakthrough discovery in human AIDS. An isolation of a new human retrovirus related to previously described Type I and II of human T-cell leukemia virus (HTLV) represents the most probable causative agent of this disease. This virus(es) called HTLV III, has the unique property of destroying the helper T-lymphocyte, which is precisely the disease-fighting cell found to be severely diminished in AIDS. Based on the incidence of antibodies to this virus, essentially all AIDS patients have been infected. Many high-risk individuals who already have T-lymphocyte abnormalities, but not outright AIDS, also have antibodies to HTLV III. It is not known at present whether infection with this virus will always result in AIDS or whether it can be self limiting. Normal individuals not known to be at risk very rarely show antibody to this virus. NCI scientists have developed human cell lines which produce large amounts of HTLV III which can be used to develop rapid immunological assays to detect infection. Accordingly, blood or blood products used for transfusions could be routinely checked to prevent potential future disease transmission. With the availability of modern biotechnology, vaccine production may be possible in the near future for the protection of high-risk groups. These findings represent the first real hope of eradicating this very lethal and progressive disease.

Question: Is research moving in the direction of multiple causes, or do you think it's still possible there may be a single cause, such as a virus?

Answer: As indicated above, a new human retrovirus related to Types I and II of HTLV has been isolated and is the most probable causative agents of AIDS.

Question: How much will you spend on AIDS in fiscal 1985 and what will the money be used for?

Answer: In 1985, NCI estimates an expenditure of $15.1 million for AIDS research. This will continue to support research project grants, contracts and intramural research, an effort to deal with all aspects of the AIDS enigma. Some examples of research will are anticipated at this time include:

Nutritional assessments of AIDS patients--This is important because cachexia is a serious clinical problem which has not been adequately studied in AIDS patients;

Study of "differentiating agents" and low-dose chemotherapy in AIDS patients with malignancy--Because of the severe suppression of immune functioning associated with conventional chemotherapy, study of alternative approaches to therapy of malignancy in AIDS patients would be very valuable. There is little data available on the immunologic effects of conventional chemotherapeutic agents, leaving little guidance for developing therapeutic regimens for treatment of AIDS-associated malignancies;

Support to identify the etiologic agent of AIDS--In a recent discovery, the isolation of a new human retrovirus, related to previously described Type I and II of human T-cell leukemia virus (HTLV) and called HTLV III, represents the most probable causative agent of AIDS. Research will be undertaken to better understand the role of the virus in human disease through biological, molecular biological and epidemiological studies;

Support will be given for a systematic evaluation of the cancer experience of individuals who have AIDS or who are at risk for AIDS, as well as for identification of the specific determinants of risk or each form of cancer. While attention has focused on Kaposi's Sarcoma and opportunistic infections as clinical manifestations of the Acquired Immune Deficiency Syndrome (AIDS), there are reasons to believe, on both biological and epidemiological grounds, that an increase of lymphomas and other malignancies will occur in groups at high-risk for AIDS, especially homosexual men;

Studies concerned with epidemiologic investigations of HTLV to include Jamaica and Panama and also some disease-oriented studies in South Africa, Peoples Republic of China, and other countries in Africa; and

If the ongoing studies on retroviruses suggest a direct causal relationship to human AIDS, attempts at early vaccine production and trial will be done. NCI has the mechanism in place to generate, in our pilot plants, adequate amounts of material for trial purposes.

## SPECIAL EXPERTS

Question: What is the effect of including special experts in personnel ceilings? Does it deprive you of hiring others whom you badly need?

Answer: Since special experts are not tenured appointments, including them under a normal federal employment ceiling could discourage individuals from accepting what may be an uncertain term of employment.

However, during the formation of the FY 1985 budget, the Institute was allocated some FTEs to partially cover the special expert positions. Therefore, for the current period, we have some limited ability to hire for badly needed positions.

Question: To what extent would taking special experts out of your personnel ceilings increase -- or not increase -- your budget?

Answer: There would not be a dollar impact on the NCI budget whether experts were included or excluded from the personnel ceiling. All salary expenses have always been budgeted within each program.

Question: What report or bill language is necessary to keep special experts outside of your regular personnel ceilings?

Answer: In previous Committee Reports on the NCI appropriation, language has been included which specified that special experts were not to be included within the personnel ceilings. As we understand it, these reports expressed the Committee's intent regarding the markup of the Bill. Exclusion of special experts from the regular personnel ceilings beyond the legislative ceiling of 151 would require more specific action.

## BUDGET ISSUES

Question: Your budget request is for $1.1 billion, or about $24 million more than your fiscal 1984 appropriation.

How does this request compare with your so-called by-pass cancer budget that goes only to OMB? Is it less?

Answer: The Administration's request for NCI in fiscal year 1985 is $1,101,069,000, while the 1985 NCI By-Pass Budget which was developed prior to the completion of Congressional action on the 1984 level, is $1,189,000,000. The Administration's request is lower by $87,931,000.

Question: What is the usefulness of that By-Pass budget -- you really only defend the President's request, don't you?

Answer: The National Cancer Act of 1971 (P.L. 92-218), was enacted to strengthen the NCI so as to more effectively carry out a national program to combat cancer. This Act stipulates that the Director, NCI should submit the By-Pass budget directly to the President for review and transmittal to the Congress. The By-Pass document allows the Institute the opportunity to present, in conjunction with its Advisory bodies, a "professional judgment" budget which cannot be modified by reviewers outside the Institute. Both budgets are available to the President and OMB as they deliberate on determining the "final" level that NCI will defend before the Appropriations Subcommittees of the Congress.

Question: The Subcommittee is aware that over the past several years, NCI has done some "stretching" of research funds to support what it considers to be an optimum number of investigators. To what extent has this been done by providing a smaller amount of funds per grant than recommended by peer review study sections and by Congress?

Answer: Over the past two fiscal years (FY 1982 and FY 1983), NCI faced budget levels which would have resulted in the funding of considerably fewer competing research project grants than had been supported in prior years. Acting upon the advice of the President's Cancer Panel, the National Cancer Advisory Board (NCAB) and well respected members of our grantee community, we reduced funding for both noncompeting and competing grants in FY 1982 and for competing grants in 1983.

We note that these advisors were not pleased to consider this option. Under the funding constraints of those years and given the other program priorities, they concluded that cancer research would be best supported in this way.

These reductions represented reductions from levels recommended by the initial review groups (study sections); however,since the full peer review process includes the review by the National Cancer Advisory Board, we considered that the full peer review included concurrence to reduce grant awards in order to support more cancer laboratories. In fact, there was a substantial benefit resulting from this stretching of grant funds - we were able to maintain 200 laboratories working on cancer research during this period of budget constraints, laboratories which would otherwise have stopped work.

Question: We understand you asked OMB for a $20 million construction budget, but wound up getting $2.5 million which was below your FY 1984 level. What are the facts--and what pressing matters did you need the additional $17.5 million for?

Answer: In early 1978 at the request of the National Cancer Advisory Board, through its Subcommittee on Construction, the NCI conducted an evaluation of the then current and future funding needs for upgrading of cancer research facilities to meet safety codes and expanding research activities. The evaluation addressed the funding needs in four categories.

- Clinical research facilities
- "Standard" research laboratories
- Biohazard containment facilities
- Animal facilities

The survey indicated that the construction needs totalled $221 million. Of that amount, the respondees estimated that they would look to NCI for about $97 million. When asked to project ahead five years, the community estimated a need for $20 million per year in construction funds. Therefore, in our FY 1985 By-Pass Budget, we requested $20 million for construction, which is substantially different from the Administration's request to OMB.

In FY 1985, we will continue to address the most critical facilities needs in the areas of clinical and standard research laboratories, biohazard containment and animal facilities.

Question: We understand that the proposed funding of cancer center core grants will be about $1 million below the fiscal 1984 level. Why is this and what is the effect on these centers?

Answer: The level of funding for cancer centers in FY 1985 reflects that the Institute's top priority is the funding of investigator-initiated research project grants. Within the budget level requested, the centers program would be reduced $1 million from FY 1984 levels. Overall, the centers program will be funded at approximately nine percent below study section recommended levels.

## NUTRITION RESEARCH

Question: The Subcommittee is aware that the American Cancer Society has begun a campaign for a diet designed to reduce the risk of cancer. The Society reportedly urges Americans to consume less fat, alcohol and smoked foods in favor of eating more high fiber foods as well as food rich in vitamins A and C.

What is your view as to the importance of the Society's proposals?

Answer: We are in complete agreement with recommendations of the American Cancer Society, particularly the recommendations to reduce dietary fat and increase intake of fruits, vegetables, an cereal grains which will provide increased intake of dietary fiber, vitamin C, and vitamin A. We currently estimate that 30-35 percent of cancer incidence may be related to diet. Thus, appropriate changes in diet may be expected to have a significant impact to reduce the incidence of cancer in this country. The National Cancer Institute is developing food choice lists, shopping hints, menus, and instructional materials which can be used by the general public to make changes in their diet in accord with our current dietary recommendations. However, we are unsure as to how effective the campaign of the American Cancer Society and the informational campaigns of the National Cancer Institute will be in inducing the population to change dietary habits, and we are also uncertain as to the time course over which changes in diet might be expected to result in reductions in cancer incidence. These questions require further research.

Question: We are aware that NCI also is at work on nutrition research. Tell us about your efforts and indicate what progress you are making in the battle against the cancers that are susceptible to diet modifications.

Answer: Our efforts can be divided into two broad categories: diet intervention and chemoprevention. In our diet intervention studies we are studying the impact of changes in diet on the incidence of cancer in target populations. In the chemoprevention area we are prescribing specific chemicals in precisely defined amounts to be taken by target populations. The chemoprevention agents that are being prescribed in these clinical trials are currently micronutrients but the scope of chemoprevention will, in the future, include other chemicals which may not be nutrients.

Nutrition research aimed at reducing the risk of cancer may be divided into three categories: laboratory research, epidemiology research, and clinical trials. Laboratory research includes studies of diets in animals aimed at reducing the incidence of cancer in these animal models, studies of the mechanisms by which different dietary components may inhibit or prevent the carcinogenic process, and more detailed study of the composition of foods so that in the future more precise and refined dietary recommendations may be possible.

In epidemiology research we are collecting and analyzing information on the dietary habits of different population groups to draw correlations between specific dietary patterns and risks of cancer. In addition, we are performing analyses on biologic samples such as blood, urine, hair, and toenails, which may reflect dietary intake and correlating this information with subsequent risk of developing cancer of specific sites. We are also supporting the development of an international food composition data system which will further refine our ability to analyze epidemiologic data.

Clinical trials of diet for cancer prevention is a new area of emphasis within the National Cancer Institute. Initial efforts are getting underway this year and are focusing on a 20 percent fat diet with the end point of reduction in the incidence of breast cancer and the improvement in the prognosis of women who have already developed breast cancer. These initial trials will document our ability to elicit compliance with a dietary regimen under the intense encouragement of a clinical trial. This will give us an increased understanding of how we may be able to influence dietary habits of the general population. These studies will also further clarify the precise effect of diet on cancer incidence and the time course over which diets may impact on cancer incidence. Although the evidence associating dietary fat with increased incidence of cancer of the breast, colon, prostate, and endometrium is very strong, these clinical trials may be viewed as the "clincher" studies of the association of dietary fat and cancer of these sites.

Several case-control studies assessing the role of diet in cancer etiology have been initiated in areas with high mortality rates for specific cancers to seek explanations for the elevated rates. In a study of esophageal cancer among black men in Washington, D.C., heavy alcohol consumption and poor nutrition were determined to be the major risk factors. In another case-control study of oral and pharyngeal cancer in women in North Carolina, fruit and vegetable consumption was found to be consistently associated with reduced risk. Snuff and tobacco use were the major risk factors for oral and pharyngeal cancer within this population. It was found that their impact could be reduced, but not totally eliminated, by diet. Confirmatory studies to refine the relationships of diet to cancer noted in these two studies are now underway.

Some of our studies are designed to test specific hypotheses about diet and cancer in human populations. Both vitamin A and its precursor carotene in plant sources of food have been suggested to protect against cancer. Preliminary results from a case-control study of lung cancer among white men in New Jersey suggest that carotene intake rather than that of vitamin A is associated with reduced risk. To further assess this hypothesis, case-control studies of lung cancer in New Jersey blacks, New Jersey women, and Texas men and women are now in progress.

Colon cancer and breast cancer are usually considered to be the most common diet-related cancers. However, the strong associations with fat and fiber intake that have been predicted are not consistently detected in case-control studies. Therefore, two somewhat unusual case-control studies of these two cancers have been designed. The study of colorectal cancer is based on the observation that colorectal cancer mortality rates are higher in the Northeast and North Central states than in the South. In the areas of Florida with high immigration from the North, however, colorectal cancer rates seem to resemble those of the South, even among the older residents. The question being investigated is whether people who migrate from the North to the South can acquire the lower colorectal cancer risk of the South within a few years and what aspects of lifestyle are being changed. Preliminary analysis suggests that Northerners moving at a young age (less than 50 years old) may acquire the lower Southern risk; but whether age is an absolute requirement or simply represents a time beyond which individuals are no longer willing to adopt new lifestyles, is not yet clear. The study of breast cancer is being done among Oriental women who have migrated to either California or Hawaii and who are experiencing the elevation in risk of breast cancer that occurs as an Oriental diet is changed to a Western diet. Dietary patterns in childhood, adolescence, and adulthood are being assessed so that the possibility of breast carcinogenesis being usually sensitive to diet at an early age can be evaluated. Because of the heterogeneity of diet among Oriental-Americans, it may be possible to clarify the specific aspects of diet that increase the risk of breast cancer in Western diets.

NCI also supports laboratory investigations searching for mechanisms of cancer induction which may be caused by a variety of dietary constituents such as fats of varying sources and saturation levels, proteins of various types and levels, fiber, nitrosocompounds, mycotoxins and other naturally occurring carcinogens. Inhibitors of carcinogenesis, compounds associated with the gut and the influence of microflora are also being investigated. In addition, studies which focus on specific dietary factors, such as nutrients or micronutrients, are being conducted.

Studies are also underway to evaluate the influence of nutritional modulation on carcinogenesis. In one study in mice, dietary restriction started at or beyond mid-adulthood slowed immunologic aging, inhibited cancer and prolonged life. Previous studies had produced similar effects in mice fed restricted diets since weaning. Adult-onset underfeeding provides a model of cancer inhibition which can be studied to identify contributing immunologic and endocrinologic influences.

We believe the results of these investigations will be of great interest to the members of the health care professions and to the general public and will further enhance our ability to encourage changes in the diet of the general population.

Question: We understand you propose to spend $49.5 million on nutrition research in fiscal 1985, about a $4.5 million increase over the current year. Some $ 31.2 million of your proposal would go to chemoprevention. What is chemoprevention?

Answer: Chemoprevention is a term we have applied to the use of chemicals for the prevention of cancer. This includes selected vitamins, minerals and synthetic analogues of these compounds. Our current clinical studies in chemoprevention focus on micronutrients or synthetic derivatives of micronutrients, but we plan in the future to consider non-nutrient chemicals for chemoprevention as well. Most of our research program in chemoprevention is in the areas of laboratory research and clinical trials but as in the nutrition studies discussed above we draw important leads from epidemiologic studies as well. Laboratory research in chemoprevention includes test-tube research and research in experimental animals. It is possible to study carcinogenesis in tissue cultures and to study the ability of specific chemicals to prevent carcinogenesis in tissue cultures. In addition, we are studying chemicals in animals aimed at identifying chemicals which may prevent cancers induced by chemicals, viruses, radiation, or spontaneously developing cancers. Part of the increase in our budget would go to increased studies in laboratory animals aimed at identifying those chemicals having the greatest potential for prevention of cancer so that these chemicals could then be used in chemoprevention clinical trials. In addition, we would plan to increase support for clinical trials with particular emphasis on development of new chemopreventive agents and application of agents which are currently under study to additional high-risk groups. Although we have a large number of chemoprevention trials currently in progress, we do not have any studies focusing on prevention of bladder cancer and this is cited as an example of development of studies for a specific target high-risk group. An example of a new agent which we plan to develop further in 1985 is 4 hydroxy-phenyl retinamide, which is a synthetic analog of vitamin A, and which in animal models has been shown to be more effective than vitamin A in preventing cancer of the breast and bladder with less chance of toxicity than occurs with use of vitamin A.

Question: What clinical trials do you have planned or underway in the nutrition field and how will they be affected by your budget request for fiscal 1985?

Answer: The clinical trials planned or underway are displayed on the list below. The two trials listed with the low fat diet will begin as small scale feasibility studies during fiscal 1984 and we plan to expand them to full scale implementation during fiscal 1985 under the current budget request. In addition, we plan to increase our activities in chemoprevention as discussed under the previous question.

NCI-Funded Prevention Research
Clinical Intervention Trials

| Target/Site/High-Risk Groups | Location |
|---|---|
| Cervix - cervical dysplasia<br>Inhibitory Agent: retinal acetate | Univ. of Arizona Health Science Center |
| Cervix - cervical dysplasia<br>Inhibitory Agent: retinyl acetate | Albert Einstein College of Medicine, NYC |
| Colon - familial polyposis<br>Inhibitory Agent: synthetic vitamin A (isotretinin) | West Virginia Univ. |
| Lung Mesothelioma - persons with asbestosis<br>Inhibitory Agent: vitamin A | Univ. of Washington, Seattle |

| Target/Site/High-Risk Groups | Location |
|---|---|
| Lung - chronic smokers<br>discontinued smokers<br>Inhibitory Agent: vitamin A | Fred Hutchinson Cancer Research Center, Seattle |
| Skin - basal cell carcinoma<br>Inhibitory Agent: 13-cis-retinoic acid | Univ. of Alabama |
| Skin - basal cell carcinoma<br>male military and VA hospital patients<br>Inhibitory Agent: 13-cis-retinoic acid | NCI, Bethesda, MD |
| Colon - colon polyps<br>Inhibitory Agent: beta-carotene | Univ. of Illinois, Chicago |
| Lung - male smokers<br>Inhibitory Agent: beta-carotene (synthetic) | National Public Health Institute of Finland, Helsinki |
| Skin - basal cell carcinoma<br>Inhibitory Agent: beta-carotene<br>vitamins C, E | Memorial Hospital for Cancer, NYC |
| Skin - non-melanoma skin cancer<br>Inhibitory Agent: beta-carotene (synthetic) | Dartmouth College |
| All sites - physicians<br>Inhibitory Agent: beta-carotene | Harvard Medical School<br>Brigham and Women's Hospitals, Boston |
| Skin - albinos<br>Inhibitory Agent: beta-carotene<br>canthaxanthin | Muhimbili Medical Center, Tanzania, East Africa |
| Colon - familial polyposis<br>Inhibitory Agent: vitamins C, E, wheat bran | Memorial Hospital for Cancer and Allied Diseases, NYC |
| Lung - chronic smokers<br>Inhibitory Agent: vitamin $B_{12}$<br>folic acid | Univ. of Alabama |
| Cervix - cervical dysplasia<br>Inhibitory Agent: folic acid | Hutchinson Cancer Research Center, Seattle |
| All sites - dentists<br>Inhibitory Agent: selenium<br>vitamins A, E, $B_6$ | Brigham and Women's Hospitals, Boston |
| Esophagus - general population, rural China<br>Inhibitory Agent: multiple vitamins | NCI/The Cancer Institute, Chinese Academy of Medical Sciences, Beijing, China |

| Target/Site/High-Risk Groups | Location |
|---|---|
| Esophagus - esophageal dysplasia<br>Inhibitory Agent: multiple vitamins | NCI/The Cancer Institute, Chinese Academy of Medical Sciences, Beijing, China |
| Breast - women at increased risk for breast cancer<br>Inhibitory Agent: low-fat diet | Cooperative Group |
| Breast - stage II breast cancer<br>Inhibitory Agent: low-fat diet | Cooperative Group |

## SMOKING AND CANCER

Question: The Subcommittee is curious about how much research you do in the smoking area in light of continued concern about the relationship of smoking to cancer.

We understand your FY 1985 budget proposes to spend around $21 million on smoking, but that some $13 million of this amount relates to behavioral studies. Doesn't that imply that you are doing relatively little basic research on the cancerous effects of smoking?

Answer: The 1964 Surgeon General's Report on Smoking concluded that "...cigarette smoking is causally related to lung cancer...(and) the risk of developing lung cancer increases with the duration of smoking and the number of cigarettes smoked per day and is diminished by discontinuing smoking." In the intervening 20 years, additional thousands of scientific investigations have confirmed this conclusion and provided additional evidence concerning the relationship of cigarette smoking to lung cancers. Finally, thousands of other studies have implicated smoking as a cause of cancer of the larynx, oral cavity, and esophagus, as well as being associated with cancer of the urinary bladder, kidney, and pancreas. Faced with this mass of overwhelming evidence linking smoking and cancer in various sites, the NCI has indeed begun to focus less on basic studies aimed at further establishing the causal relationship of smoking and cancer and more on the cancer control goals of preventing cancer through smoking prevention and cessation.

This does not mean, however, that the value of basic research in the smoking area is in any way being diminished at NCI. Rather, it is being redirected to focus on such areas as the carcinogenic potential of involuntary inhalation of tobacco smoke, the possible carcinogenic effects of tobacco additives and smokeless tobacco, and screening for inhibitors of N-nitrosamine carcinogenesis.

NCI continues to conduct epidemiologic research to further quantify the role of smoking in the etiology of various cancers. Ongoing studies of cancers of the lung, larynx, oral cavity, pharynx, esophagus, bladder, kidneys, pancreas, stomach, and uterine cervix all have a component to evaluate smoking. A number of studies examine the ways in which smoking interacts with occupational and other factors (such as radiation exposure in Japan) and also assess the role of smoking upon lung cancer risk.

Continuing epidemiologic studies have shown that the risk of developing lung or larynx cancer continues to be decreased among long-term (10+ years), filter cigarette smokers when compared to long-term non-filter cigarette smokers. Research has indicated that the smoking habits of women are becoming more similar to those of men; however, proportionately more women choose filtered cigarettes, in general, and very low-tar cigarettes (1.0 mg. tar), in particular, than men. Women also begin the cigarette habit approximately three years later than their male counterparts. Studies have also shown that the mean number of cigarettes smoked per day is higher in smokers of low-yield cigarettes at all ages and in both sexes. No differences in mean duration of cigarette smoking or in age at starting to smoke have been observed. These observations provide some evidence for "compensation" in smokers of low-yield cigarettes.

Another area of intense lung cancer research concerns whether and how dietary factors, in particular nutrients such as vitamin A, may be protective against lung cancer. Such research must incorporate data on smoking in order to adjust for its effect, and also in order to see if the possible benefit of diets high in beta-carotene or retinol is greater for smokers, as some preliminary data suggest.

The effect upon non-smokers of exposure to others' cigarette smoke is still not clear.

In recent years some epidemiological studies have indicated an association between involuntary or passive smoking and an increased risk of cancer. Many chemical substances of mainstream smoke have been reported in sidestream smoke, with some substances released into the sidestream smoke in markedly higher amounts than into the mainstream smoke. The actual absorption of individual smoke components by non-smokers in smoke-filled environments has been reported only for a few components. The pattern of involuntary inhalation of tobacco smoke is probably different from that of voluntary inhalation by the smoker. Therefore, the question arises whether a person exposed involuntarily and for many years to the smoke of others inhales sufficient amounts of carcinogens to elicit a carcinogenic response. NCI will issue a request for applications in the near future to stimulate research to assess the effect of involuntary exposure to tobacco smoke on cancer risk. The acquisition of the additional data from these NCI studies should help clarify the relation, if any, to lung cancer.

NCI is currently supporting a number of studies that are designed to determine carcinogenic or cancer-promoting effects of constituents in both particulate and gaseous phases of cigarette smoke and to assess and mitigate health effects attributed to smoking and tobacco use. One representative study is designed to: (1) provide quality-assured data on the deliveries of selected chemical constituents in smoke from experimental and commercial cigarettes; (2) develop validated methods for quantitative determinations of chemical smoke constituents which are present in very low quantities; and (3) develop methods to establish the relationship of smoke exposures and resulting dose of smoke constituents experienced by the smoker.

Other studies are concerned with determining the mutagenic and/or carcinogenic effects of tobacco specific nitrosamines metabolic products of nicotine. Such studies will lead to methods for determining the daily intake of nicotine, tar and other smoke constituents from cigarette smoking and smokeless tobacco consumption. Additional studies have shown that at least three of the tobacco specific nitrosamines are carcinogenic in mice, rats, and hamsters. These studies are continuing with emphasis on: (1) the formation and/or occurrence of selected tobacco smoke carcinogens derived from N-nitrosamines and (2) the underlying mechanisms of tobacco carcinogenesis.

NCI is also conducting research in the effect of smokeless tobacco upon cancer risk. Earlier NCI studies showed conclusively that snuff use could cause cancers of the cheek and gum. Indeed, the risk of these ordinarily rare cancers was increased nearly 50-fold in long-term snuff users. Ongoing research is attempting to further define the risk of oral cancer in terms of duration and intensity of both snuff and chewing tobacco usage. The effort is of particular importance because of the recent upswing in the use of smokeless tobacco in the U.S., and the adoption of this habit by large numbers of teenage boys across the country.

Question: Why are you working on behavior -- isn't that something better done by other components of the Public Health Service, such as the Centers for Disease Control?

Answer: The focus of the NCI Smoking, Tobacco, and Cancer Program is on cancer control, which is the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad systematic application of the research results. As such, it is essential that NCI support behavioral studies because a significant change in smoking behavior of the U.S. population will be required in order to meaningfully contribute to the NCI goal of a 50 percent reduction in cancer mortality by the year 2000.

Other components of the Public Health Service are, of course, not only well-qualified to carry out behavioral research in the smoking area but do so at the present time. In addition to the Centers for Disease Control, other PHS components interested in the behavioral aspects of this issue include the National Institute on Drug Abuse, the National Institute of Child Health and Human Development, and the National Heart, Lung, and Blood Institute. The NCI Smoking, Tobacco, and Cancer Program maintains regular contact with staff of the CDC and these Institutes in order to avoid any overlap in the behavioral research related to smoking that each is conducting.

However, since the NCI is the only one of these PHS components with a centralized smoking research program and because of its broad cancer control goals, it is most appropriate, from the standpoint of available resources, that this Institute conduct the most comprehensive smoking research program. Because behavioral research, particularly research carried out over a considerable period of time, as is necessary with smoking, is one of the most important activities that may be undertaken in cancer prevention, the NCI must pursue this issue.

It should be reemphasized, however, that coordination of behavioral research in smoking is essential and that the NCI will continue to maintain open and regular communication on this issue both within and outside the Public Health Service. It is only through this communication that the cancer control goal of "...an orderly sequence of research" will remain in focus.

Question: Aside from research on smoking, how much do you spend on lung cancer research and how does this relate to what you do on smoking?

Answer: Lung cancer is a major health problem in the United States. It is the leading cause of cancer death in males from age 35 on, and the second leading cause of cancer deaths in females age 35-74. Moreover, the death rate from lung cancer in both men and women is doubling every fifteen years. It is estimated that in 1984, lung cancer will exceed breast cancer as the leading cause of death from cancer among women, presumably due to the growing number of women who smoke. Overall, lung cancer is ten times more common in smokers as compared to non-smokers.

NCI will spend an estimated $43,000,000 in lung cancer research in FY 1984 and $47,000,000 in FY 1985. These figures include research in such areas as epidemiology, etiology, diagnosis and treatment, which have had a significant impact on the NCI's smoking-related activities.

The NCI is currently conducting a number of studies designed to identify and clarify risk factors for lung cancer.

For example, in 1980-1982 two population-based case-control studies of lung cancer were implemented in high-risk areas of New Jersey and the Texas Gulf Coast. The studies are designed to elucidate the interaction between diet and smoking, occupation, and residential history in the development of lung cancer.

The NCI is also attempting to evaluate the role of passive smoking in the development of lung cancer. Studies involving 94 lung cancer cases and 683 controls who never used any form of tobacco are being analyzed and total years exposure to passive smoking are being examined relative to the lung cancer experience in this population. Information is available with regard to parental smoking and the smoking of a spouse. The estimated amount and duration of exposure are being considered as well as the role of occupational and other factors in the development of lung cancer among non-smokers.

NCI scientists are also participating in international epidemiologic studies of lung cancer. A case-control study of lung cancer in Japan will evaluate passive smoking as a risk factor among women (whose exposure comes mainly in the home and is more easily quantifiable) and assess interactive effects between smoking, radiation exposure, and occupation in men. Another case-control study of lung cancer is proposed for Shanghai, Peoples Republic of China, where female lung cancer rates are twice those in the U.S., yet fewer women smoke.

Clinical studies have suggested that in the earlier stage of disease more patients are likely to be cured of lung cancer.

This has led to the hope that screening studies designed to detect early lung cancer would lead to earlier treatment and increased rates of cure.

Improved treatment initiatives have included the appropriate selection of patients for surgery. Surgery offers the best chance for cure in patients with some forms of lung cancer. Improved survival for lung cancer patients can also be expected from the appropriate integration of surgery, radiotherapy and chemotherapy in the primary management of the disease. The philosophy of multidisciplinary treatment had already shown great impact in the care or patients with an aggressive form of lung cancer called small cell cancer of the lung which is highly correlated with smoking. Untreated patients with this disease have a median survival of 6-17 weeks. Combination chemotherapy with or without radiation therapy has improved median survival in this disease to 40+ weeks, with a significant percentage of patients now achieving long term survival.

Information derived from epidemiologic, diagnostic, and treatment studies of lung cancer have greatly contributed to the development of the Smoking, Tobacco and Cancer Program (STCP). These investigations have provided the information which has resulted in the current major focus on prevention and cessation of tobacco use and the contribution of this effort to the Institute's goal of a 50 percent reduction in cancer mortality by the year 2000. Lung cancer related data such as the following have convinced the NCI that tobacco use cessation and prevention needs to be a major thrust in this area:

- Eighty-five percent of lung cancer cases are due to cigarette smoking.

- Smokers are 10 times more likely to die from lung cancer than are non-smokers.

- Lung cancer deaths, primarily due to smoking, have increased over 600 percent in the past 35 years, from 18,000 in 1950 to 118,000 in 1984.

- The five-year survival rate for cancer of the lung is less than 10 percent and has not changed in 20 years.

Clearly, the overall impact of these data, all provided through NCI lung cancer research, suggest that the most cautious approach to lung cancer is prevention and the most powerful preventive agent is either not to start smoking or to stop if one already has begun.

## MONOCLONAL ANTIBODIES

Question: The Subcommittee wishes to stay abreast of your work on monoclonal antibodies which are created by fusion of a cancer cell with a normal antibody-producing cell.

To what extent is this a "developing" technology -- and is it useful in dealing with other diseases besides cancer?

Answer: Significant strides have been made in the understanding and production of monoclonal antibodies, but this is still a developing technology. For example, in the mouse we can make unlimited amounts of a specific monoclonal antibody to essentially any antigen. Our ultimate but still elusive goal, however, will be to make human monoclonal antibodies which will be made by fusing an appropriate human cancer cell and a human antibody-producing cell. Diagnosis and treatment of patients with human monoclonal antibodies are the starting steps of the future of this technology.

At present, mouse monoclonal antibodies can already be used to experimentally diagnose and treat some human tumors. Monoclonal antibodies are made which are directed against a unique tumor-specific antigen expressed on the surface of the cancer cells but not on normal cells. The monoclonal antibody is tagged with a radioactive tracer, and as it finally homes in onto the tumor cell, the cancer can be visualized by x-ray or other radiological tests. Alternatively, the same monoclonal antibody can be tagged or armed with a drug, a poison, or a different kind of radioactive isotope. These monoclonal antibodies attach to tumor cells, and the cancer cell is killed by the toxin or the radiation on the monoclonal antibody.

Monoclonal antibodies are of key importance in our understanding of all infectious diseases as well as many non-infectious diseases which deal with abnormal immune responses, such as various phenomena of autoimmunity, or as an abnormal reaction against one's normal tissues. Major breakthroughs are expected in tissue transplantation because of monoclonal antibodies. Additionally, monoclonal antibodies are, and will continue to be, of critical importance in the developmental aspects of other forms of biotechnology as well.

Question: What can you tell us about research progress on oncogenes which we're told may carry some important secrets about how cancer develops and how its spread may be impeded?

Answer: Oncogenes are represented as about two dozen unique cellular genes found on various chromosomes. Under normal circumstances, the known products of several oncogenes are important cellular growth signals, or factors or their receptors. Studies on oncogenes have now unified our concepts as to how cancer is caused by chemicals, radiation, or viruses. It seems that the abnormal activation of one or more of these oncogenes at the molecular level is the underlying principle of cancer. Generally, several of these oncogenes are turned on in concert. The turning on occurs either by abnormal switching on of oncogenes or by a mutation in the oncogene itself. Characteristic patterns of oncogene activation are known to occur in various diseases. At times, the activation of an oncogene can be very obvious in that an oncogene is broken from one chromosome and glued to another chromosome where it comes under the influence of an incorrect molecular switch or promoter. On occasion, an oncogene in tumors is magnified many times so that it is found not as a single copy, but can exist in hundreds of identical copies. Too many oncogene copies then make an excessive amount of their protein product, which makes the cell abnormal. Because oncogenes are at the core of the cancer problem, the key to cancer will be in learning how to turn off or prevent the expression of the abnormal oncogene product.

## MONOCLONAL ANTIBODIES, ONCOGENES

Question: Bring us up-to-date on your research on interferon. Are there side-effects from interferon and, if so, do they make it any less useful as a therapeutic agent against various cancers?

Answer: Although the interferons (IFNs) are natural products, manageable toxicities have been associated with their use. The explanation for this is that IFN has been administered in superphysiologic (higher than would occur naturally) doses. The major side effects are similar to the flu and include nausea and vomiting. These symptoms are usually worse with the first dose and become more tolerable as treatment continues. Increasing tiredness is encountered in nearly all patients, becomes worse as the IFN is continued, and may require decreased doses or interruption of therapy. The dose which produces the disabling fatigue varies considerably from patient to patient. Other side effects include lowering of the blood counts, nervous system toxicity usually involving difficulty in concentrating, slow thinking, or even mild confusion. Other rare toxicities such as damage to kidney or liver may also occur. These problems can be managed with dose reduction and, in some cases, may require interruption of treatment followed by resumption of the IFN at lower doses. It is important to note that all of these toxicities are readily reversible when the IFN is stopped and that most patients who are helped by therapy can be continued on some dosage of IFN.

Despite these apparent problems, IFN has already become an important weapon in the arsenal against cancer with definite response rates established in a number of cancers. Two approaches are now under study to decrease IFN side effects without compromising, and perhaps improving, its anti-cancer activity. Lower, but still higher than naturally occurring levels, are being compared to the higher dose approach, and extremely low, near normal, doses are being tested to determine if the immune system can be altered beneficially and responses achieved.

Clinical research with IFN has progressed rapidly over the last three years, but many questions regarding optimal dose and schedule, proper mixtures of different kinds of IFN or combinations of IFN with chemotherapy and radiation therapy must still be studied. Nevertheless, it is now apparent that IFN has already been established as an important agent in the treatment of a number of cancers, even with the manageable toxicities mentioned.

Interferons have been studied now for their possible efficacy in the treatment of a wide variety of cancers. Clinical studies have been performed with both interferons naturally produced by human cells and also with genetically engineered interferons. They have been shown to cause clear clinical benefits in a large proportion of patients with the following types of cancer: lymphomas of certain types, chronic myelogenous leukemia and some other forms of leukemia. In addition, an appreciable number of patients with multiple myeloma, malignant melanoma, and kidney cancer have benefited from this form of treatment. Also a substantial number of patients with a type of cancer (Kaposi's Sarcoma) associated with AIDS (Acquired Immune Deficiency Syndrome) have responded well to treatment with interferon.

## CANCER BOARD APPOINTMENTS

Question: The Subcommittee is aware of press reports indicating some dissatisfaction with appointments to the National Cancer Advisory Board. The thrust of the criticism is that vacancies are being filled with practicing physicians rather than researchers, and that some members were selected for political reasons.

What is your response to these criticisms?

Answer: The membership of the National Cancer Advisory Board (NCAB) as mandated by the Cancer Act of 1971 (P.L.92-218) and by the 1978 amendments to that Act (P.L. 96-622) must include, as a minimum, 12 individuals possessing scientific competence "in the study, diagnosis or treatment of cancer;" there is the further requirement that at least five NCAB members are to have demonstrated expertise in environmental carcinogenesis. We feel confident that this requirement will be upheld with the nominations currently being processed by the White House.

Question: How many Board members are there; how many are researchers and how many practicing doctors; and what does the law say about the makeup of the Panel?

Answer: There are 18 Board members, appointed by the President. The law requires that not more than 12 of the appointed members of the board shall be scientists or physicians, not more than eight of the appointed members shall be representatives from the general public, and not less than five of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupations and dietary factors). Eleven of the present board members hold a medical degree. Of these, three are active research investigators; the remaining eight are involved primarily with the clinical practice of medicine. A fourth researcher holds a Ph.D.

## PREVENTION AWARENESS

Question: Doctor, we have recently heard of your new prevention awareness program. Can you tell us a little about it?

Answer: Yes, our Cancer Prevention Awareness Program was launched March 6 by Secretary Heckler. It represents a major federal effort to increase national public awareness of the possibilities for cancer prevention, and will help the American people learn what they can do every day to control their own cancer risks.

If we are to reach our goal of reducing the 1983 national cancer death rate level by 50 percent by the year 2000, individual actions must match continuing progress in cancer research. We know that nearly 80 percent of cancers are related to causes within the individual's control since many are associated with personal behavior such as smoking, eating habits, etc. Yet, a survey we conducted last year revealed that the public's view of cancer is confused and unnecessarily pessimistic. Many erroneously believe that everything causes cancer and that there is not much a person can do to prevent it.

The theme of the prevention awareness program is "Cancer Prevention: The News Is Getting Better All The Time." The program will be implemented in two phases. The first will aim to increase public attitudes regarding cancer and cancer prevention, and to influence individuals to take appropriate actions to reduce their risk of cancer. Phase I will rely primarily on mass media efforts, but will include print materials. The second phase of the program will focus on specific education programs for high-risk target audiences. These targeted programs will address risk factors such as tobacco, radiation, nutrition, occupational exposures, estrogens, viruses and alcohol.

The mass media campaign will run from February through midsummer, 1984. Then the program emphasis will shift toward populations at greater than average risk, and will encourage organizations -- especially at the local and state levels -- which serve those groups, to join the Institute in conducting cancer prevention programs.

Question: Could you explain your efforts as they relate to clinical trials for both treatment and prevention? You have initiated major efforts in this area of chemoprevention during the past year. Describe them for us.

Answer: For most of its clinical treatment research, the National Cancer Institute does not fund the operation of specific clinical trials. Instead, the NCI supports a number of clinical cooperative groups which perform cancer treatment research utilizing protocols under the cooperative agreement mechanism. Each group is organized to provide a structure for clinical researchers to collaborate in the design of clinical trials and to accrue patients for the testing of new cancer therapies. For each cancer site, there are always numerous ongoing trials which test the efficacy of chemotherapy, immunotherapy, radiation therapy, and surgery. These trials are identified by individual protocols and NCI reviews and funds approximately 600 new protocols each year. In addition, support is given to previously approved protocols which are in a continuing state of patient accrual. A clinical trial in a new area or in a new application of one of the traditional modalities of treatment is generally reflected in multiple protocols in one or more disease sites. The funding and priority assigned to each area will depend upon the quality of the applications received for cooperative agreements, grants, and contracts as determined by the scientific peer review process.

In addition to its clinical treatment research, however, the NCI supports clinical trial research in the area of prevention, which includes trials in chemoprevention. These seek to determine in humans the efficacy of agents which have been found in animals to have the ability to prevent, halt, or even reverse the malignant process. These trials include:

- efforts to evaluate the efficacy of 13-cis-retinoic acid in prevention of basal cell carcinoma;

- a nutrition intervention trial to elucidate the causes of esophageal cancer and the prospects for its prevention;

- a study to assess the effect of the combined dietary administration of ascorbic acid and alpha-tocopherol, either alone or with wheat fiber, on rectal adenomas in patients with polyposis coli who have undergone colectomy;

- a study to determine the role of vitamin A and its precursors and derivatives in preneoplastic and neoplastic conditions. This multidisciplinary research effort is investigating the effect of vitamin A and vitamin-like compounds at the biological, cellular, and clinical levels; and

- investigation of selenium and beta-carotene as potential cancer prevention agents. Beta-carotene is being studied as a chemopreventive agent in skin cancer; selenium and vitamins A and E are being studied in a population of dentists to determine their efficacy as chemopreventive agents.

## Questions Submitted by Senator William Proxmire

### NCAB VACANCIES

Question: Dr. DeVita, the scientific community has been rather critical lately of the way in which National Cancer Advisory Board vacancies have been filled. To be more precise, five outgoing Board members signed a letter to Science magazine in January that faulted the President for failing to appoint research scientists to fill Board vacancies. The letter claimed that "the quality and objectivity of the review of cancer-research proposals and the future direction of cancer research are at stake."

I understand that six Board vacancies occurred in March and that none of the remaining members have a degree in basic research. Can you tell us if any of those vacancies have been filled with research scientists?

Answer: It is true that, of the remaining members, none have primary experience in basic research. We feel confident that the nominations which the White House is considering include many fine research scientists. In this regard, the Office of the Director, NCI, has been recently informed by the White House that new appointees to the NCAB have now been selected, though the names of these individuals cannot be released at this time, pending the usual clearances.

### RADIATION EXPOSURE

Question: Last year you indicated that a portion of your epidemiology budget would be spent on collaborative research with the Radiation Effects Research Foundation in Hiroshima, Japan, to build on the organization's post atomic bomb mortality follow-up. I believe you devoted the modest sum of $259,000 to this effort.

Do you plan to continue this collaborative research next year and, if so, how much do you plan to spend on the project?

Answer: NCI plans to continue the program of collaborative research with the Radiation Effects Research Foundation, at the same level of funding.

Question: You indicated in a response for the record last year that research on the mortality and morbidity of U.S. troops involved in atomic weapons testing has been conducted by the Centers for Disease Control and the Medical Followup Agency at the National Research Council.

A recent article in the Journal of the American Medical Association reported that residents of Southwest Utah who were repeatedly exposed to radioactive fallout from nuclear detonations at the Nevada Test Site exhibited 60 percent more cases of cancer than would normally be expected. Did you support this research?

Answer: The study published in the Journal of the American Medical Association in January by Dr. Carl Johnson was supported by a grant from the Nuclear Radiation Research Foundation, and not by NCI which had no connection with the study.

Question: Do you have a mechanism in place to incorporate the results of this sort of research into your studies of radiation exposed populations?

Answer: Questions have been raised about the scientific validity of the Johnson study (e.g., the interview by Dr. J. L. Lyon in February 1984 issue of the Epidemiology Monitor, which follows. Scientists in the Radiation Epidemiology and Clinical Epidemiology and Clinical Epidemiology branches are reviewing it critically and conducting independent research to see if the reported increases are reflected in mortality data.

One of the criticisms that has been made of the Johnson study is that morbidity information from the respondents was not confirmed from medical records. Through its Surveillance, Epidemiology, and End Results (SEER) program, NCI supports the Utah State Tumor Registry, one of whose purposes is to facilitate just this sort of validation procedure.

[From the Epidemiology Monitor, Feb. 1984]

## Two Studies On Cancer Yield Contradictory Findings On Role Of Radioactive Fallout

Investigators reporting on the effects of radioactive fallout exposure among Utah residents have reached contradictory conclusions. Using NCHS data on childhood cancer mortality, NCI investigators Charles Land, Frank McKay, and Stella Machado were unable to confirm an earlier report that residence in southern Utah during the period of above ground atomic weapons testing in Nevada was associated with an increased mortality from childhood leukemia. Land and colleagues conclude that "the evidence for an increase in childhood leukemia mortality ... appears, on closer examination of available data, to be slight or non-existent."

### Positive Findings

In striking contrast, Carl Johnson of the Denver Medical Care and Research Foundation, reports that 4125 Utah residents exposed to the same fallout experienced 288 cases of cancer when only 179 were expected, an excess of 109 cases. He concludes "A burden of radiation-induced cancer throughout the state can be expected ..."

### High Stakes Contradiction

The contradictory conclusions reported simultaneously on January 13 in JAMA and Science have been heard before when both Land and Johnson testified as expert witnesses on opposing sides in a 1982 lawsuit brought against the government. Twenty-four families are seeking damages of

$75,000 to $500,000 for health effects attributed to U.S. atomic bomb testing. A decision has not been rendered by the Federal judge overseeing the nationally publicized trial, but is expected soon. If granted, the awards could lead to payments of millions of dollars to other residents of Utah, Arizona, and Nevada.

### Epidemiologist Responds

The contradictory reports are of particular interest to Utah epidemiologist Joseph Lyon and his colleagues whose earlier 1979 report of increased childhood leukemia is being refuted by Land and colleagues in their reanalysis. The Land article attributes the earlier positive findings to the use of a comparison group with artificially low leukemia rates. It states that a "more likely, but nevertheless speculative, suggestion is that the early leukemia deficit was an anomaly related to underdiagnois of leukemia or to competing mortality from other childhood diseases."

In a telephone interview with the Epi Monitor, Lyon did not disagree with Land's reanalyis as far as it went, but he pointed out that it only includes data for the period during and after the radiation exposure and not before 1950. If the low rates during this earlier period are in fact real, then the Land study omits significant observations. Furthermore, Lyon remarked that an approximately eight fold relative risk in 1959-1967 for 10-14 year-old children who lived through the highest exposure period 1951-1958 is ignored by the summary procedures used in the Land study. Lyon agrees that cancer rates are low in his Utah population (one half of U.S. rates from 1940-1980) but does not believe this is due to under-diagnosis. "Rates have jumped only once in this period," he said, "and this was in the immediate post-fallout era."

### Other Criticisms

In response to criticisms about statistical methods, Lyon readily admits to one error mentioned by Land and colleagues, but states that their 1979 New England Journal paper was reviewed heavily by qualified statisticians, some of whom even reworked the data. Their conclusion--"That's about what you do," said Lyon in quoting the reviewers. Regarding the dosimetry issue so critical to these studies, Lyon points out that his independent measures support earlier reports of heavier exposure in the southern cohort he studied. There are however differences in the results of physical measurements taken by different techniques, and these will have to be resolved.

### JAMA Study

Although the Johnson study is more consistent with the conclusions from Lyon's data than the Land study, the Utah epidemiologist is quicker to criticize its methods. Because the data were collected by interview without independent validation of cancer diagnosis from medical records, and because participants were reportedly shown an anti-nuclear film before completing questionnaires, Lyon believes the Johnson study represents an overdiagnosis of cases. To support his contention, he notes that the usual higher male to female ratio is reversed in Johnson's data, and the overall mortality rate is much lower than expected--both of which suggests reporting of non-cancer cases as cancer.

### More Definitive Study

Lyon and his co-workers are currently carrying out an NCI funded state-wide study of cancer incidence among Utah residents which he believes will yield more precise findings and the only definitive data on the health effects of atomic bomb testing in this area. Results are expected by mid 1987.

Question: Can you tell us what conclusions you have reached, if any, about the morbidity and mortality of those exposed to nuclear detonations?

Answer: The most severe effects of A-bomb exposure are injury from blast and heat; radiation sickness (which can be fatal) due to radiation from the explosion itself or from radioactive fallout; and death. Long-term survivors of an atomic bomb explosion may be at increased risk of disease, primarily cancer, resulting from radiation exposure. The magnitude of this increased risk depends upon the amount (dose) of radiation received. For doses on the order of one of two rads the excess risk is probably too small to be noticable against background disease levels, but for doses of hundreds of rads substantial excesses have been documented for leukemia and cancers of the female breast, thyroid gland, lung, stomach, colon, esophagus, and other organs. Other late effects, whose risks also depend upon radiation dose, include radiation cataracts and, for persons exposed prenatally, mental retardation and small head size.

The average radiation dose to the 285,000 living persons identified on the 1950 Japanese national census as having been within 10 km. of the Hiroshima or Nagaskai A-bomb explosions was 17 rads. Based on extensive mortality studies through 1978 of a sample of 82,000 survivors by the Radiation Effects Research Foundation in Japan, there have been about 190 excess leukemia deaths among all survivors, a 95 percent increase over the 200 deaths not related to radiation, and about 340 excess deaths from cancers other than leukemia, as compared to about 10,000 not caused by radiation (a 3.4 percent increase). The percentage increase in risk has of course been higher among the more heavily exposed survivors, and lower among those with less than 17 rads.

In terms of time after exposure, leukemia was the first cancer to be seen at elevated levels among the Hiroshima and Nagasaki survivors. An increase occurred within three-five years after the bombings, peaked, and then declined until, by 1978, it appeared to have virtually disappeared. The increase and subsequent decline were especially marked among the youngest survivors, and were more gradual among older survivors. Other forms of cancer took longer to show up in excess, and this excess has persisted.

## NCI - POSITION SHIFTS

Question: Dr. DeVita, last year's budget justifications indicated that you planned to allocate 92 positions to cancer control in fiscal year 1983. Your current justifications indicate that you moved an additional 31 positions above your initial estimate into this area last year and decreased staff devoted to research and resource development. Can you tell us why you made this shift?

Answer: During the last 18 months several new research areas have emerged which required shifting staff from existing to new research efforts. Among our highest priority efforts are programs in prevention of cancer which are funded predominately through the Cancer Control activity. Other areas receiving increasing emphasis are epidemiology and immunology in response to launching a new research program in Acquired Immune Deficiency Syndrome (AIDS).

Question: Perhaps your biggest position loss in fiscal year 1984 will be taken in biological carcinogenesis. Your original 1984 estimate called for 261 positions. Your current 1984 estimate is 203 positions. How will this reduction affect your biological carcinogenesis program?

Answer: Initiating new research programs within existing resources has required reallocating of positions among our existing programs. In addition, reviews of program content during 1983 resulted in reclassifying programs concerned with monoclonal antibodies from biological carcinogenesis in the Cause and Prevention thrust to the immunology program in the Cancer Biology thrust. As research programs evolve and advances are made, it frequently occurs that a program becomes closely allied with programs in other thrusts or divisions. Through our annual review of scientific programs, these areas are identified and, where appropriate, shifted from one scientific category to another and/or from one administrative area to another in an effort to make most efficient use of resources and to allow for scientific cross-fertilization by co-locating similar scientific research programs.

### NCI - POSITIONS OTHER THAN PERMANENT

Question: Dr. DeVita, last year's justifications indicated the Cancer Institute would spend $15.2 million on positions other than permanent in fiscal year 1984. That estimate has been changed to $19.8 million -- an increase of more than 30 percent. These funds will support 136 more full time equivalent positions than you originally budgeted for.

Can you tell us what has caused this cost and position growth?

Answer: The increase of 136 full time equivalent (FTEs) workyears and $4.6 million for other than permanent employment in the 1984 estimates developed for the 1984 and 1985 Congressional Justifications reflect the effects of increased employment levels in 1983, the October 1984 payraise, and FTE workyears for overtime which were not included in the initial 1984 estimate.

### PRINTING AND REPRODUCTION

Question: You originally planned to spend $6,104,000 on printing and reproduction in fiscal year 1984. Your current estimate is $3,562,000. What printing projects have you been forced to delay or abandon because of this reduction?

Answer: NCI has not delayed or abandoned the publication of activities that either promote the latest advances in cancer research or are important educational tools of which the public should be aware. If it is necessary, we will achieve reductions in other areas in order to disseminate the latest information on cancer research and prevention.

At the time of the development of the 1984 Congressional Justification, the Institute's projection of printing needs resulted in a $6 million estimate. Subsequent to the submission of the 1985 budget and as a result of a continuing review of requirements within the Institute, including those for printing, NCI requirements resulted in a slight reduction of funds.

### NCI - OTHER SERVICES -- OTHER

Question: On page 30 of your justifications under "Other Services" you list a subcategory of expenditures termed "Other". What does this subobject class designation cover?

Answer: The subcategory "Other" under the general heading "Other Services" includes obligations for services not classifiable under other categories in the object class schedule. The major items in this area are for support of international activities such as the International Cancer Research Data Bank; repairs and alterations to buildings, scientific, and office equipment; training of employees; automated data processing; telecommunications; storage of household effects for employees being transferred from or to other geographical areas; support of conferences and workshops; payments to volunteers for medical research; animal holding and bleeding services; biomedical engineering instrumentation; and glassware, photography, graphics and media for various intramural research projects.

Question: I note that your original 1984 expenditure estimate for this subobject class of $46,563,000 has been revised upward to $51,227,000. Can you tell us why?

Answer: The original estimate for 1984 of $46,563,000 in "Other Other Services" was based on the budget level of $986,681,000. The actual 1984 appropriation was $1,077,279,000. Thus, in the development of the 1984 column of the 1985 Congressional Justification, the 1983 actual obligations ($50,837,000) were utilized as the basis for estimating obligations for 1984 in this area so that it is approximately equivalent to the 1983 level, allowing only a small growth of 0.8 percent.

## NCI - SUPPLIES AND MATERIALS

Question: Your initial "supplies and materials" estimate for fiscal 1984 was $30,082,000. That has been scaled back to $23,257,000. Please tell the Committee what expenditures you decided to forego.

Answer: Controllable expenditures in object classes such as supplies and materials, equipment, printing and transportation have been reestimated in the development of the 1985 budget and held to minimal increases over the 1983 actual obligations level. A continuing review of the Institutes needs and priorities resulted in the redistribution of funds within the in-house object classes in order to counterbalance extramural program expenses and mandatory personal services increases.

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## QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

Question: In last year's report, we included language urging the Institute to make a greater effort to see that the benefits of cancer research extend to all areas of the country. We directed you to utilize cancer control outreach programs at comprehensive cancer centers so that communities in which they are located could benefit from their expertise, thus freeing up Community Cancer Oncology Program monies for those communities in which such research benefits would otherwise be unavailable.

We did this after learning that several CCOP grants were awarded to hospitals and clinics in cities in which large cancer centers were already located. In a letter I received from Dr. Frelick, Director of CCOP, I was told these CCOP grantees served populations "frequently not exposed to state-of-the-art cancer care, although their proximity to cancer centers might have made it possible."

Please advise us as to what you are doing to make community care more possible at the centers and also what efforts you are making to use CCOP to distribute the benefits of cancer research nationwide.

Answer: The centers are involved in several projects which should enhance community cancer care. These include providing consultants to community hospitals to participate in local tumor board conferences. A recent survey indicates that possibly 258 such contacts are made per month. In addition, many centers through their Cancer Information Service (CIS) programs are available for either patient or physician telephone requests. In some centers, toll free networks have been established specifically for physician consultation purposes.

Many centers conduct oncology workshops, symposia or meetings devoted to cancer problems oriented to community physicians. Some centers affiliated with medical schools provide teaching opportunities for community physicians, sending students to community hospitals for clinical experience. Local oncologists interact with the students and the medical school.

Since the mid-seventies, through NCI Cooperative Group Outreach Program (CGOP), most of the Cooperative Groups, whose core members generally come from the centers, have developed relationships with affiliated community hospitals and physicians interested in participating in the research clinical trial program of the NCI. The Cooperative Group Outreach Program reaches over 500 community hospitals.

The CCOP program, initiated in the fall of 1983, goes an additional step and provides an opportunity for the many recently trained oncologists now in community practice to develop and maintain relationships directly with the centers and cooperative groups as research bases. The CCOP program enables cancer centers to establish direct relationships with the community components to conduct research. A total of 62 CCOPs in 34 states were funded. Geographic consideration was a criterion. Thirty CCOPs are affiliated with 17 cancer centers throughout the country and cooperate with them in carrying out research protocols.

As these center-community relationships become more firm, a good basis will be laid for further networking to include projects for studies in prevention as well as the current emphasis on clinical research trials.

The 62 CCOPs are composed of 267 separate components (hospitals or physicians' offices). Some of these "components" are geographically distant from the award recipient. For instance, one CCOP, based at the Oshsner Clinic in New Orleans includes components in Baton Rouge, Louisiana and Hattiesburg, Mississippi. Thus, the effect of the CCOPs is more widespread than the 62 awards would seem to indicate.

In addition to CCOP, the Cooperative Group Outreach Program reaches over 500 community hospitals, most of which are located in smaller communities. They participate in the same clinical research activities, but on a smaller scale than the CCOPs.

## NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

## STATEMENT OF DR. CLAUDE LENFANT, DIRECTOR

**ACCOMPANIED BY:**

**DR. JAY MOSKOWITZ, ASSOCIATE DIRECTOR FOR SCIENTIFIC PROGRAM OPERATION**

**DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. Next, we will hear from the National Heart, Lung, and Blood Institute.

The Institute is charged with responsibility for making further progress against those major killers, heart disease and stroke, and with advancing scientific knowledge in the areas of lung and blood diseases.

We are told that the last decade has seen the death rates from heart disease fall by 25 percent and stroke by 40 percent. According to NIH, these figures translate into at least 1 million lives saved.

The budget request for the Institute is almost $719 million, or about $16 million more than the fiscal 1984 appropriation level.

Here to present the Institute's request is Dr. Claude Lenfant, the Director. Welcome to the proceedings.

Dr. LENFANT. Thank you, Mr. Chairman. With me is Dr. Jay Moskowitz, who is our Associate Director for Scientific Program Operation.

[The statement follows:]

## STATEMENT OF DR. CLAUDE LENFANT

It is my pleasure to address this committee once again on behalf of the National Heart, Lung, and Blood Institute. As you may recall from past testimony, our Institute's mandate encompasses research and training programs to seek the causes of heart, lung, and blood diseases, to improve their diagnosis and treatment, to reduce mortality, and to prevent these diseases whenever possible. The Institute is also responsible for programs concerned with blood resources.

I am pleased to report that there have been many exciting areas of progress against these diseases during the past year.

- Definite proof that lowering of blood cholesterol in men with high cholesterol levels reduces risk of coronary heart disease has been obtained in the 10-year Coronary Primary Prevention Trial supported by the Institute. This finding has important public health implications.
- The Coronary Artery Surgery Study (CASS), another clinical trial, has found that patients with mild to moderate angina pectoris and asymptomatic survivors of myocardial infarction can safely defer coronary artery bypass surgery until symptoms become severe. A significant reduction in medical care costs is expected as a result of this finding.
- Important advances in the delineation of complex molecular pathways of pulmonary endothelial cells will contribute to the understanding of lung function in normal and diseased states.
- Reliable noninvasive procedures have been developed to identify children with sickle cell disease who are at risk for life-threatening infections.

With these advances in mind, the magnitude and significance of the responsibilities of the Institute can be gleaned from figures for morbidity, mortality and economic costs of the diseases within the Institute's purview. Each day an estimated 3,400 Americans--more than two each minute--experience a heart attack. Approximately 60 million have hypertension, which means that almost one-quarter of the U.S. population suffers from this major risk factor for heart attack and stroke. Chronic obstructive lung disease, which today is the fastest rising cause of death in this country, affects 10 million Americans. Thirteen million units of blood or blood products are transfused into more than 3 million patients each year in the United States and represent a major contribution to health. Overall, diseases within the Institute's responsibilities represent a cost of over $124 billion annually.

The Institute continues its commitment to a balanced program that draws upon a variety of support mechanisms to acquire and validate new knowledge and to transfer promising findings to community settings. We find reason for optimism in the dramatic and continuing decline in death rates from coronary heart disease and strokes which compares favorably with trends in death rates from noncardiovascular diseases. Progress is clearly being made in reducing disability and mortality in many of these diseases. Some important areas of progress are highlighted below.

## KNOWLEDGE ACQUISITION

Acquisition of new knowledge through basic research continues to be the bedrock of the Institute's programs. The Institute allocates approximately 70 percent of its extramural funds to support the highest merit investigator-initiated research proposals. These continue to be the major support mechanism for studies concerned with the etiology and pathogenesis of diseases of the heart, blood vessels, lung and blood. Some examples of new areas of basic research deserve mention:

Hypertension: It has long been accepted that hypertension involves complex relationships among the sympathetic and parasympathetic components of the autonomic nervous system and humoral transmitters. It is now increasingly evident that the central nervous system has direct effects in regulating blood pressure as well as its indirect effects through the autonomic system. These relationships are being elucidated through the techniques of neurobiology, and such basic studies are providing important insights into how behavioral factors and humoral mechanisms are interrelated in determining control of blood pressure. The use of immunohistochemical techniques to map the distribution of central pathways through which the brain controls blood pressure has revealed that discrete brain areas are responsible for this regulatory function. A notable discovery has been the identification of peptides in the brain that were formerly believed to be secreted only by the gut, pancreas, kidney or pituitary gland. These peptides have now been found in the nerve tracts in the brain that control blood pressure, where they act as neurotransmitters.

Oxygen Toxicity: Basic research is providing valuable clues to a problem associated with the therapeutic use of oxygen in clinical conditions where lung function is impaired, or in environmental conditions where the supply of oxygen may also have toxic effects when given in high concentration or under high pressure. The clue to this apparently anomalous situation is that some biochemical changes result in release of oxygen as a "free radical", which is an unstable, highly reactive form that can induce cell damage, particularly in the lung.

The opportunities for studying and elucidating this problem have been extended since it has been learned that free radicals of oxygen are also released in such conditions as exposure to radiation, ozone, oxides of nitrogen in polluted air, paraquat and some anticancer drugs. The variety of conditions under which the free radicals are released give reason for optimism that it will be possible to identify the underlying biochemical mechanisms and thus to intervene to prevent untoward reactions during oxygen therapy.

Acquired Immunodeficiency Syndrome (AIDS): The NHLBI is concerned with the safety and efficacy of the nation's blood supply. Although the transmission of AIDS by blood has not been established unequivocally - since the number of cases of apparent transfusion-association of the disease is still small - nevertheless the Institute has taken the initiative by supporting two substantial programs in AIDS research related to transfusion medicine. The NHLBI has solicited, received, and reviewed applications for investigator-initiated research designed to develop an assay to detect the carrier state in AIDS, in order to allow blood banks to screen donors for the presence of a possible transmissible agent in the blood. Such a test is urgently needed but not yet available.

In another program, recipients of blood and blood products will be carefully followed in a multi-center prospective study in an effort to ascertain the extent and influence of changes in the immune defense system that might be brought about by chronic transfusion therapy especially insofar as these changes might be linked to the subsequent development of AIDS.

## KNOWLEDGE VALIDATION

Clinically relevant knowledge acquired through basic research is validated through clinical studies. Numerous promising approaches to diagnosis and therapy are currently being explored. These include drugs that are effective in preventing the harmful--sometimes life-threatening--abnormalities of heart rhythms, and the use of "smart" pacemakers to detect and correct such disturbances. To dissolve or remove clots that obstruct the arteries of patients with heart attacks, promising approaches include thrombolytic therapy to dissolve the clots, and balloon catheters to remove the obstruction by mechanical means. The use of lasers is a newer approach now being explored.

Primary Prevention of Coronary Heart Disease: A ten-year clinical trial, the Coronary Primary Prevention Trial (CPPT), has shown for the first time that the reduction of elevated blood cholesterol results in a reduction in risk for heart attack. It was carried out in 12 clinical centers in the U.S. and Canada. A total of 3,806 men who were healthy except for elevated blood cholesterol were randomly assigned into two groups. Each group received instructions for a moderate cholesterol-reducing diet. One group then was administered a cholesterol-lowering drug, cholestyramine, and the other group received a placebo. Compared with the placebo group, the drug-treated group experienced a 24 percent reduction in fatal heart attacks and a 19 percent reduction in nonfatal heart attacks.

Infections in Sickle Cell Disease: Children with sickle cell disease have a predisposition to life-threatening infections, which occur in about 10 percent of children with this disease. A major advance in combating these infections was the development in 1970 of a pneumococcal polyvalent vaccine that increases antibody concentrations in children over age 2. For some pneumococcal types, however, antibody levels have been inadequate at all ages and serious infections still occur.

Because susceptibility to the deleterious effects of infections is related in large measure to loss of splenic function in the first 3 years of life, spleen scans using 99m technicium colloid have been used to measure splenic function. There is now a new technique that is sensitive, economical, expeditious and provides semiquantitative information on splenic function. This promising approach uses interference phase-contrast microscopy to enumerate vesiculated red blood cells. This cell type appears to increase when splenic function is lost. The increase in number occurs progressively and more rapidly in children with homozygous sickle cell disease than in children less severely affected. This technique provides clinicians with a reliable noninvasive procedure that enables them to assess the need for antibodies to provide early protection against infections.

Coronary Artery Surgery Study: The results of a recently completed clinical trial have made a valuable contribution to the problem physicians face in deciding whether or when to recommend bypass surgery for their patients with coronary artery disease. The Coronary Artery Surgery Study (CASS) has provided a scientific basis for making such judgments. In a study involving 780 patients randomized with regard to elective bypass surgery or deferring surgery until symptoms worsened, we are pleased to be able to report that there was no significant difference in survival between the surgically and medically treated patients. Six years after the inception of the study, 90 percent of the medically assigned and 92 percent of the surgically assigned patients are alive. Moreover, no significant differences between the two groups were uncovered in any of a large number of subgroups analyzed. As was expected, the surgically treated patients experienced greater relief from angina during the followup phase of the study, were able to exercise longer and needed fewer drugs, but there were more hospitalizations in this group. The two groups did not differ in recreational activity or in the ability to return to work. The favorable outlook for patients with moderate angina and of patients who were asymptomatic survivors of myocardial infarction is reassuring to both patients who are facing the question of whether to undergo bypass surgery and their physicians.

## KNOWLEDGE TRANSFER

The Institute continues actively to transfer the knowledge that has been acquired and validated. Some examples follow:

Collaborating with the Private Sector: From the late 1970s to the early 1980s the National Heart, Lung, and Blood Institute (NHLBI) supported three major research efforts for high blood pressure control at the worksite--efforts involving employees of the Ford Motor Company, the State of Maryland, and Westinghouse. These projects demonstrated the effectiveness of interventions at the worksite as compared to community-based efforts. The positive results of these undertakings and other related research were highlighted at a national conference for Fortune 500 executives sponsored by the Institute, General

Motors and Metropolitan Life. This conference was entitled "Worksite Health Promotion and Human Resources -A Hard Look at the Data". It focused on existing evidence supportive of disease prevention and health promotion at the workplace and highlighted many areas where important questions still need to be answered.

Self-Management of Asthma: The Institute has supported the development of three model educational programs to teach children with asthma and their parents how to manage their condition. Results from these studies have shown increases in the child's self-management, decreases in days lost from school, and less anxiety on the part of the family. By means of a series of workshops, the Institute is working with the American Lung Association to make these programs available to hospitals, clinics, voluntary associations, physicians, nurses and health educators. We are also supporting research on asthma self-management through general relaxation techniques or through biofeedback. An educational program for adults with asthma is currently being developed and evaluated to teach the requisite skills for self-management. An important feature of this program is the use of the peak flowmeter so that subjects can measure their airway resistance daily and thus learn to recognize when an attack may develop. The NHLBI and the NIAID have just completed an evaluation of educational programs and materials for self-management of children with asthma.

Mr. Chairman, the 1985 budget request for the National Heart, Lung, and Blood Institute is $718,852,000, an increase of $15,671,000 over the comparable FY 1984 level. I will be pleased to answer any questions the committee may have.

## BIOGRAPHY OF DR. CLAUDE LENFANT

October 12, 1928, Paris, France

Education. B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956.

Professional History. 1957-1958, Research Fellow, University of Buffalo, New York. 1958-1959, Research Fellow, Columbia University, New York. 1959-1960, Assistant Professor of Physiology, University of Lille, France. 1961-1965, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1966-1967, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1968-1971, Associate Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1970-1972, Acting Associate Director, Collaborative R&D Program, National Heart and Lung Institute, NIH. 1970-1972, Associate Director for Lung Programs, National Heart and Lung Institute, NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1972-1980, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH. 1981-1982, Associate Director for International Research, NIH. 1981-1982, Director, Fogarty International Center for Advance Study in the Health Sciences, NIH. 1982-Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional Organizations. Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Federation for Clinical Research, French Physiological Society, International Federation for Medical Electronics, American Society of Zoologists, Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Sciences.

Honors, Awards. Thesis Prize, University of Paris, France, 1956. Commendation Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHEW, 1974. University of California, Los Angeles, Regents' Professor, 1978. Testimonial Dinner, American Thoracic Society, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Honorary Professor, National Yang-Ming Medical College, Taipei, Taiwan, 1980. Honorary Professor, Unidersidad Peruana Cayetano Heredia, Lima, Peru, 1981. Elected Institute of Medicine, National Academy of Sciences, 1983. American Heart Association Scientific Councils "Distinguished Achievement Award", 1983.

### SUMMARY STATEMENT

Dr. LENFANT. I'd like to take a minute or so to describe some of the studies that we have completed this year. Foremost, is the study that Dr.—excuse me, Senator Proxmire referred to——

Senator WEICKER. Listen, we don't pretend on this side of the tables to be doctors. [Laughter.]

Now, on the other hand, we do have Dr. Stockman and Dr. Meese and Dr. Baker. You know, that's one of my concerns, as a matter of fact.

But we don't pretend that kind of expertise. We expect that expertise from those of you on the other side.

### CHOLESTEROL AND DIET STUDY

Dr. LENFANT. You heard from him, and the discussion that followed was essentially what I wanted to point out. I would like, however, to add a little to what was said earlier.

First of all, the low cholesterol diet that we are advocating and urging the public to follow is not a punitive diet. It is a moderate and balanced diet which I think is very important to convey to the American public.

With regard to informing the public of the outcome of our studies, I would like to mention a program that has just been completed with Giant Food. That is, during the last few years we have had with that organization, a program called "Food for Health." And regarding the low cholesterol diet, we are just about to initiate a new program called know your cholesterol that will be comparable to the National High Blood Pressure Education Program that has been ongoing for 10 years and has been very successful.

Senator WEICKER. Excuse me just a minute, Doctor. Are more people standing out there? There are seats here at this end of the table. Please go ahead and avail yourselves of them. There is at least another seat over here and one over there.

Go right ahead.

### CORONARY BYPASS SURGERY

Dr. LENFANT. Another study that I would like to mention compared medical and surgical treatment of ischemic heart disease symptoms, such as angina. The outcome of this study has shown that a great number of patients could, indeed, defer coronary bypass surgery until their symptoms reach the point whereby surgery becomes a necessity.

### SICKLE CELL

I would also like to mention that through technical refinement and better understanding of sickle cell disease at the molecular level, we have developed a number of reliable, not unduly expensive, and very practical techniques that allow the prenatal diagnosis of the disease. This technology is now being tested by our Sickle Cell Center network.

## PULMONARY DISEASE

Turning now to the Pulmonary Disease Program, 2 years ago we reported to this committee the outcome of a clinical trial to test the adequacy of steroids to prevent the occurrence of respiratory distress syndrome in premature infants. One question that was left unanswered was whether or not this treatment may have some adverse effects on the development of the infant.

I am pleased to inform you that this phase has now been completed and that, in fact, there are no adverse effects. Therefore, we now have an effective means to prevent respiratory distress syndrome in premature infants.

Finally, I would like to mention that we have completed a study for teaching asthmatic children to take responsibility for their condition. The interesting outcome of that study is that in the year following the program these children averaged 12 fewer school day absences and had an average of five fewer emergency room visits.

Most of the studies that I have briefly mentioned here had their inception as a result of basic fundamental research that began many years ago. All have had or will have major clinical applications and will, we believe, give opportunities for considerable medical cost savings. This point relates to the question that Senator Proxmire was asking earlier.

Thank you, Mr. Chairman.

## CHOLESTEROL AND DIET EDUCATION

Senator WEICKER. What do you expect to be telling the American people vis-a-vis cholesterol and diet?

Dr. LENFANT. A number of events are being planned that will eventually lead to informing the American people. The first step is to assess how the results of the cholesterol study impacts on the beliefs of practicing physicians.

Prior to reporting the study, we assessed the beliefs of physicians with regard to cholesterol and diet. Now that the study has been out for a couple of months, we are planning to repeat the assessment to see if some modifications have occurred. This is the first step.

The second step is to have, within a couple of months, a conference to bring together a group of experts to assess the impact of the study and what they feel should be communicated from that study to the public. Then, a few months later, we will have what we call a consensus development conference that will allow participation by all interested parties, and assurance that everybody comes to the same conclusions.

As I mentioned earlier, we are planning a public education program called "Know Your Cholesterol." Basically, we would like to encourage the American public to be concerned about cholesterol.

Last year, Mr. Chairman, we talked about high blood pressure. I don't know if you recall that, but let me point out some differences. For high blood pressure, you can go in airports, in department stores or in grocery stores and find a machine where you can stick your arm in and read your blood pressure on a screen. For cholesterol it's more complex. It's also more expensive and it requires the help of a physician. We would like to see the American public be concerned about, and develop an awareness about the need of knowing what their cholesterol level is.

Senator WEICKER. You think that politically you're going to be able to do this? In other words, any sort of an information program such as you're talking about is going to cost money.

Obviously, at least from what I've seen in the studies, you're going to impact on various elements of our economy which won't be without political ramifications. How is the meat industry going to react? How is the egg industry in this region going to react?

We go right down the line here. You can't disseminate unless you have the money to disseminate this information.

Dr. LENFANT. Well, having the money to disseminate information is one thing, but I really would like to first address the concern of some of the industries in this country, as the milk and meat industry and others like these.

We are not advocating the elimination of these products from one's diet. We are advocating a prudent diet that includes eggs, that includes red meat, but not in uncontrolled quantities.

Now, with regard to the money——

Senator WEICKER. I mean, I think you should. You know, these are matters that if, indeed, they have come to a scientific conclusion, we shouldn't be sticking our head in the sand.

I'm not, in any way, trying to intimidate you.

Dr. LENFANT. No.

Senator WEICKER. I'm just saying, do you feel they are of such conclusive proof that the Government should step out there, now, and tell the American people what the risks are?

Dr. LENFANT. Well, I don't feel intimidated at all. In fact, I'm very pleased to hear you ask about this because if the ultimate outcome of research is to do good for the American people, here is a superb example of research that began 15, 20 years ago at a very basic level and now provides information which is understood and has tremendous value for the American people and others in the world.

So we feel very strongly about that and we are interested in developing an education program which, indeed, will cost money; but everything costs money these days. The point is that unless we have this education program, the important information from this research will take a much longer time to get out there.

Senator WEICKER. Do you have the money in this budget for this information program?

Dr. LENFANT. We have some to initiate it at a low scale and we'll do the best we can.

Senator WEICKER. Do you need any more studies, or do you have information now that should be disseminated to the American people? Or do you need more studies?

Dr. LENFANT. The answer is yes on both counts. We do have information that we can pass on; but as with any good scientific studies it opens new questions that need to be addressed. That's how we move ahead.

So, therefore, the answer to your two questions is yes.

Senator WEICKER. I think in this particular case you might let the committee know what you feel is needed to do the proper dissemination job.

### BUDGET IMPACT

I think I'll sum the questions that I addressed to Dr. DeVita into one question, which I'll ask you and the other directors of the institutes. Where does the administration's budget, either cuts or infinitesmal increase, hit you the hardest in your Institute?

Dr. LENFANT. Well, I would say in three areas.

The first one is that, as you probably have seen from the budget submission, the number of new and competing research grants will be decreased in our Institute, from 729 this year to 682 new research grants for next year. That's a decline of 47 grants.

The second one is that, as you know, Mr. Chairman, our Institute has a fairly large center program which we believe is vital to our activities and to the success of our programs. Our centers program does research that is not done through the other support mechanisms. Our budget is level for next year compared to this year.

Third, you asked earlier about the number of trainees. Our Institute will fund 210 fewer trainees in 1985 than we are able to fund this year. We consider this to be an important element in our programs.

### CORONARY BYPASS SURGERY

Senator WEICKER. In the matter that you alluded to as far as heart surgery is concerned, it seems to me I read articles on this of recent vintage which indicate that too much surgery is being done in this area that could be handled in other ways. Is that correct?

Dr. LENFANT. That's correct. Allow me to qualify that.

For many patients you would never dream of coronary surgery. For other patients you have no choice. Surgery is what you have to do because their condition is so bad.

Now, there is a large number of patients somewhere in the middle for whom it could be surgical treatment or medical treatment. It's a matter of choice by the patient who may have heard of his neighbor who had surgery and is doing very well, so he pressures the physician for surgery, or it's a matter of choice on the part of the physician.

Our study addressed the group in the middle, where you could go one way or the other. What we came out saying is that in many of these patients there is no need to rush into surgery. They could wait until it becomes absolutely necessary, which may be 5 or 10 years in some of these patients. In the United States the number of these patients is considered to be about 25,000 a year as compared to nearly 175,000 people who have coronary bypass surgery each year. So it's a small fraction, but if you translate these 25,000 surgical procedures into dollars, you are talking about $500 to $600 million. This is big money. It's almost the budget for the Institute. [Laughter.]

## ARTIFICIAL HEART

Senator WEICKER. You told us that as a clinical experiment the artificial heart case of Dr. Clark was a success in that the patient's life was extended beyond what had been anticipated and the device functioned well.

A year later, do you still feel the same way about this procedure and do you know of any plans for further experimentation with the artificial heart?

Dr. LENFANT. Our view today is that much has been learned from the case that has been done. I think it would be premature to end research on the artificial heart at this time. I think that more cases have to be done so that we can learn more about the possibilities, as well as the problems of artificial heart surgery. You probably saw in the newspapers not too long ago that Dr. Shumway, the leading cardiovascular surgeon at Stanford University in California, made some fairly negative statements about the artificial heart.

My response is that I don't know that the opinions of Dr. Shumway are shared by everybody!

Now, the second part of your question is: What's next? As you know, a few weeks ago the University of Utah submitted a new protocol to the FDA for approval. When I heard about this I expected approval to be imminent. But then, 2 days later, I saw in the newspaper that it had been refused.

I must say I do not know what the status of the approval by the FDA is today. My expectation is that it's going to come, and that a few more cases will be done and, I believe, should be done before we pass a definitive judgment on this practice.

Senator WEICKER. How much is the Heart Institute spending on this research at present?

Dr. LENFANT. In 1983, the moneys that we spent for what we call the Circulatory-assist Artificial Heart Program were $9 million. Now, this includes much more than the artificial heart itself. It includes other devices which are used for circulatory assist as well.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. All right. I have other questions for response to the record. Thank you very much, Dr. Lenfant.

Dr. LENFANT. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: There are several steps in the formulation of the budget and the Institute provides information for each step. This year the final decisions on the 1985 President's Budget were made in consultation with the Secretary and members of her immediate staff including the Assistant Secretary for Health . After decisions on total amounts were made final, the Institute received information about the total amount and how increases over the 1984 appropriated levels were to be distributed by mechanism. The Institute had an opportunity to make certain adjustments within specified limits.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: This budget permits the Institute to maintain programs that merit continued support and to expand research in the highest priority areas. It maintains scientific momentum at an acceptable, but less than ideal, pace.

Question: To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer: The Institute will reduce competing research project grants approximately 7% from projected study section recommended levels and noncompeting research project grants by approximately 13% from committed levels. It is important to note, however, that even at these reduced levels the average cost of new and competing grants will have risen 22% since FY 1983 and noncompeting grants will have risen 27% since FY 1983. Other competing and noncompeting grants will be reduced 4.7% from expected current service levels. Although it is not possible to identify specifically research that will be delayed or eliminated, reductions of this kind are certain to slow the pace of research programs somewhat. The Institute will endeavor to make these reductions in a way which minimizes their impact on future progress.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84?

Answer: In FY 85 the Institute will maintain the same number of centers at the same dollar level as the FY 84 level. Inflation, however, will cause a slight loss in purchasing power which means the amount of research activity on center grants will decline slightly. The Institute will negotiate this reduction with grantees in an attempt to minimize the impact on their research programs.

Question: What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: The Institute plans to enhance the basic and clinical research activities of Specialized Centers of Research (SCOR) by adding demonstration and education research activities to selected centers and thereby establish National Research and Development Centers. Under the President's Budget, the Institute will need to negotiate other SCOR grants by 7% in order to fund three National Research and Development Centers (NRDC). This program is expected to facilitate the transfer of knowledge gained through basic and clinical research into prevention programs and new treatment methods.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: The President's Budget permits the Institute to support 1409 full time training positions (FTTPs) in FY 1985, a reduction of 211 from the FY 1984 level of 1620 FTTPs. This decrease is part of an NIH-wide policy to support 9,000 such positions in FY 1985.

The impact of this reduction on future heart, lung and blood research is that it will reduce the number of clinically trained investigators willing to pursue research careers. The Institute will attempt to effect the proposed reduction in a way which minimizes the impact on the number of clinically trained people in our research training programs.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: The Institute will need $72,166,000 above the President's Budget to maintain its programs at the FY 1984 level. This estimate assumes that the Institute would support noncompeting research project grants at or near committed levels, the same number of competing research project grants as in FY 1984, the same number of research trainees as in FY 1984, a 4.9% increase in other extramural support mechanisms to cover inflation, and sufficient increases for intramural research and research management and support to cover mandatory cost increases and anticipated cost increases resulting from inflation.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it?

Answer: The Institute's share of the proposed full time equivalent reduction is 41. These reductions will be made in groups of personnel that do not have permanent appointments. We are currently studying the situation to determine the exact positions in our Institute to be affected by the reduction.

Question: With what effect on research?

Answer: It is difficult to assess the precise impact these reductions will have on our programs. The Institute will attempt to implement the reductions in a way which minimizes the impact on research in progress and on the effective management of our organization.

## ADVANCES IN HEART DISEASE

Question: During the 1970's, the death rate from heart disease fell 25 percent and the death rate from stroke fell a significant 40 percent, we are advised. It appears this translates into at least one million Americans living today who otherwise might have died. What accounts for these gains?

Answer: In the past 20 years the death rate from heart disease declined dramatically. Both primary prevention and improved therapy for heart attack victims undoubtedly are playing major roles in this decline. However, their relative contributions remain unknown. The treatment of heart attacks has been improved through earlier hospitalization, and improved overall hospital care particularly better control of rhythm disturbances. Prehospital cardiac arrest has improved in a number of communities because of better training for emergency medical personnel and cardiopulmonary resuscitation initiated by members of the general public. Coronary artery bypass surgery which improves the quality of life also yields an increase in life expectancy in some patient groups. The routine management of persons with heart disease has been aided by drugs for treating angina pectoris, congestive heart failure and rhythm disturbance, which may in varying degrees impact upon mortality, and certainly impact upon the quality of life. Public awareness of heart disease risk factors has caused changes in lifestyle which may have contributed to a lesser incidence, that is, new cases of heart disease, although national morbidity statistics are not available to precisely assess the effects of such changes. For example, smoking has decreased in all segments of the population except young women; dietary changes have taken place in the nation as a whole which could be expected to decrease blood cholesterol; and exercise is more widely practiced. Cardiovascular health consciousness has become important in the American lifestyle, which is in part due to health education programs. Moderate and high blood pressure is now much more widely and effectively treated, which has a proven impact upon stroke and heart disease mortality.

A downward trend in stroke mortality has been apparent for more than 50 years. The downward trend in the stroke death rate appears to have accelerated. The reasons for the acceleration are not completely clear, but certainly, management and rehabilitation of the stroke victim has improved greatly. Since there is a suggestion that stroke incidence is down, even more attention must be paid to risk factors and prevention. In this regard, it is important to note that data from the Framingham Study indicate a greater contribution to stroke by hypertention than by other risk factors. In addition, the Veterans Administration Cooperative Study and the Hypertension and Detection Follow-up Study leave little doubt that treatment of hypertension can prevent stroke. To the extent that hypertension causes stroke and stroke mortality, its effect should be declining. Not only has effective hypertension therapy been available for the past 20 years, and evidence of its efficacy in preventing stroke been clear for almost 10 years, but hypertension awareness, detection and control has increased greatly, because of the nationwide voluntary, private-sector and federal-sector coordinated National High Blood Pressure Education Program, which began in 1972.

Question: You're not saying that with all this progress we can now relax our efforts to combat cardiovascular disease, are you?

Answer: To relax our efforts now would ignore the enormous burden these diseases still impose on individuals and the nation as a whole. Heart disease ranks as the leading cause of death and reason for hospitalization (except for childbirth) and stroke is still the third leading cause of death. These diseases, together with all cardiovascular diseases, account for nearly one-half of all deaths and rank as the leading cause of major illness and disability. National health expenditures for cardiovascular patients amounted to $38 billion in 1981. An additional $59 billion was lost to the economy because of work-loss days through illness and premature death from these diseases.

Despite improvements, there are still 50 million cigarette smokers, at least 25 million persons with high levels of serum cholesterol, and nearly 23 million persons with untreated or uncontrolled hypertension. Reductions that have been made in these risk factors undoubtedly have helped to reverse the upward trend in heart attack mortality and accelerate the decline for stroke. But, there is much room for additional gains. Similarly, the new technologies in cardiovascular disease treatment and aggressive case management seem to be paying off. Their utilization needs to be expanded and cost reductions achieved.

There are potentials for further reductions in death rates. The U.S. still has a heart attack death rate that exceeds that in all but a few westernized industrial nations. Some states in the U.S. have participated less in the mortality declines and have rates much higher than the average. Some high risk groups such as middle-aged men (heart attacks) and blacks (hypertension) need special research efforts. We know much about the epidemiology and natural history of heart disease in the white population, but know little about blacks and other racial groups. To assess the nature of the recent death rate declines and geographic distribution, relationships between risk factors and heart disease need to be investigated in various communities in the nation and then linked to the varying occurrence rates of the disease as measured in surveillance prgrams. Indeed, the Institute is planning to launch a comprehensive surveillance program for just this purpose.

Question: How much of the gain we have made can be attributed to changes in lifestyle, such as attention to diet and regular exercise?

Answer: We believe that available data are inadequate to measure the relative contributions to the decline in cardiovascular mortality that may have been made by changes in diet, exercise, smoking, and other components of lifestyle thought to affect these diseases. The Center for Disease Control has estimated that over 50 percent of cardiovascular mortality is due to people's lifestyles as opposed to factors of human biology, health systems, or the environment. A respected investigator has estimated that 26 percent of the recent decline in mortality from coronary heart disease was due to reductions in serum cholesterol, 28 percent due to reductions in cigarette smoking, and 12 percent due to treatment of hypertension. The remainder was attributed primarily to improved treat ment.

While we agree with these assessments in general, such estimates are quite speculative. The Institute's forthcoming Community Surveillance Program will eventually permit much improved quantification of the various contributing factors.

Question: America now seems to have a mania for exercise. Everywhere you go, day or night, summer or winter, you see people running, running, running. Does all of that running really help ward off heart attacks?

Answer: Running, aerobic dancing, and participation in fitness clubs and sports have clearly proliferated greatly in recent years, and these activities do promote cardiorespiratory endurance. Of course, those who take up regular vigorous exercise are also likely to adopt other good cardiovascular health habits. But, the overwhelming epidemiological evidence, after controlling for these other factors, show significant benefit in heart disease risk for the exercisers as compared with nonexercisers. There is convincing evidence that exercisers have fewer heart attacks and lower blood pressure than those who do not exercise regularly and vigorously. Middle aged men and women apparently are participating in these activities, so it is likely that heart attacks are being prevented and a contribution to the recent decline in mortality may have been made.

New studies on the offspring of the original Framingham cohort are underway to further examine the contribution of exercise to the prevention of coronary heart disease.

## AIDS AND BLOOD TRANFUSIONS

Question: A major priority of this Subcommittee has been the support of research into the causes and treatment of Acquired Immune Deficiency Syndrome (AIDS). A specific concern of the public's is the possible risk of innocently becoming infected with AIDS through the transfusion of blood. How significant is this problem?

Answer: While extensive research is still ongoing and no final conclusions have been reached regarding the cause of AIDS and its transmission, there is a suggestion that on rare occasions the disease may be transmitted through the use of blood or blood products. The rare occurrence of transfusion-associated AIDS is evidenced by the small number of reported cases. Less than 50 blood recipients have been reported to have developed AIDS over the three year period since AIDS was first recognized. During that time, more than 35 million blood transfusions have been administered. While AIDS represents a serious public health problem, the risk of acquiring the disease following blood transfusion is extremely low.

Question: What screening methods are used in an effort to eliminate high risk donors from giving blood that could be contaminated with AIDS? Are they working?

Answer: The major blood banking organizations have instituted educational programs informing blood donors who belong to any of the known high-risk groups for AIDS of the potential risk to recipients of their blood and urging them to refrain from donating blood.

Donor screening personnel are also trained to recognize early signs and symptoms of AIDS. Donor medical histories include specific questions that elicit information on possible exposure to patients with AIDS or a history of symptoms that are compatable with AIDS or a pre-AIDS state.

The New York Blood Center is currently exploring the effectiveness of their donor self-exclusion program. Their preliminary studies indicate that, based upon the presence of certain common virus markers in the serum of individuals, there is a difference between the population that is self-excluding and the population that is not. Moreover, the donor population that is now giving blood differs from donor populations prior to the self-exclusion program. The present donor population has apparently segregated itself as evidenced by a major change in the sex distribution of donors and a 12 percent decrease in the proportion of male donors between the ages of 21-36.

Question: What research do you have underway that may lead to effective tests of blood for AIDS contamination?

Answer: The National Heart, Lung, and Blood Institute recently began an investigator-initiated research grant program to develop tests to identify carriers of AIDS. Seven research grants have been awarded to investigators at Stanford University Blood Bank, Palo Alto, California; VA Medical Center, San Diego, California; AMC Cancer Center, Lakewood, Colorado; University of Colorado, Denver, Colorado; Uniformed Services University of Health Sciences, Bethesda, Maryland; Irwin Memorial Blood Bank, San Francisco, California; and Southwest Foundation for Research and Education, San Antonio, Texas.

When an agent has been identified and proven to be the cause of AIDS, the Institute will assess the effectiveness of methods to detect this agent in blood, identify the prevalence of the agent in the blood donor population, explore methods to remove or inactivate the agent and explore ways to improve the management of the Nation's blood resources to effectively utilize new research findings as they become available.

Question: Do blood substitutes now being developed offer any hope as an alternative in this area?

Answer: The red cell substitutes currently under investigation are not far enough along in their development to be considered as viable alternatives to blood or blood products. During the past three years, a commercially prepared perfluorochemical substitute, trade name Fluosol-DA, has been undergoing human clinical trials in the United States. Alpha Therapeutics Corporation, a subsidiary of Green Cross Corporation of Japan, is currently supporting a trial involving the use of Fluosol-DA as a red cell substitute, primarily in surgical patients. Alpha Therapeutic recently submitted a New Drug Application (NDA) for Fluosol-DA to the U.S. Food.and Drug Administration; however, the data submitted failed to substantiate that the product met safety and efficacy requirements and, therefore, the NDA was denied. Alpha is continuing its studies in this area. There are presently no other red cell substitutes ready for clinical trials in humans.

## CHOLESTEROL LEVELS

Question: We understand you recently completed a study aimed at showing the link between cholesterol levels in the blood and heart attacks. What are the results of the study?

Answer: In the Lipid Research Clinics Coronary Primary Prevention Trial (LRC-CPPT), treatment with cholestyramine reduced coronary heart disease. When all men in the cholestyramine group were compared with all men in the placebo group, regardless of the amount of medication taken or the amount of dietary change made, the rate of fatal and non-fatal heart attacks was 19% lower in the cholestyramine group. This difference was statistically significant. Similar differences were seen for other indications of coronary heart disease. There was 20% less angina (effort-related chest pain) in the cholestyramine group. In addition, in the cholestyramine group 25% fewer men showed an abnormal response on their exercise electrocardiograms, and 21% fewer men required coronary artery bypass surgery.

A major finding of the LRC-CPPT is that the greater the reduction in blood cholesterol, the greater the reduction in heart attack rate. For men who were able to take the full prescribed daily dosage of six packets of cholestryamine and to follow the LRC-CPPT diet, their blood cholesterol level commonly fell by 25%. The heart attack rate for these men was about half that of the men whose cholesterol levels remained elevated because they were unable to take the drug or follow the diet. Men who took less than the full prescribed dose of cholestyramine showed less blood cholesterol lowering and the reduction in their heart attack rate was not so marked.

Question: What sort of dietary modification would help to halt the buildup of fatty deposits on blood vessel walls?

Answer: Dietary modifications are aimed at lowering blood cholesterol levels, specifically the cholesterol carried by the low density lipoproteins (LDL cholesterol). This reduction can be accomplished by limiting the amount of fat, saturated fat and cholesterol in the diet, increasing complex carbohydrate and maintaining a healthy weight.

In practice, a cholesterol-lowering diet limits the intake of animal products that contain saturated fat such as fatty meats and whole milk dairy products. Instead, lean meats, poultry and fish, low fat dairy products and dried beans are used as a protein sources. Low fat or skim milk is substituted for whole milk. Total intake of fats and oils is reduced and limited to those that are primarily unsaturated, such as vegetable oils and soft margarines. Foods that are high in cholesterol, primarily egg yolks and organ meats, are also limited. Fruits, vegetables and whole grain cereals are righ sources of complex carbohydrate, and should furnish about half the calories in the diet.

Question: What does the study tell us about the relative importance of dietary modification versus taking drugs that reduce cholesterol?

Answer: The LRC-CPPT was not designed to assess directly whether cholesterol lowering by diet prevents coronary heart disease. Nevertheless, its findings, taken in conjunction with the large volume of evidence relating diet, plasma cholesterol levels, and coronary heart disease, support the view that cholesterol lowering by diet also would be beneficial. Because it is unlikely that a conclusive study of dietary-induced cholesterol lowering for the prevention of coronary heart disease can ever be implemented, the findings of the LRC-CPPT represent an important signpost on this issue.

The LRC Program's report suggested that the results of the study should be applicable to anyone in the upper 20% of the population distribution for plasma cholesterol levels (cholesterol > 240 mg/dl). It is expected that the majority of these people could be treated with diet alone in view of its efficacy in lowering blood cholesterol levels, its safety, and its low cost compared with drug treatment.

## BYPASS SURGERY

Question: Each year thousands of Americans have coronary bypass surgery at costs that apparently run into the billions of dollars. We understand that you have done a study to determine whether bypass surgery prolonged life in patients with certain types of heart disease. What did you find?

Answer: The Coronary Artery Surgery Study (CASS) is an NHLBI-supported multicenter, randomized trial involving eleven outstanding institutions. The trial findings were reported in the November 1983 issue of the journal Circulation.

The trial included mildly symptomatic patients with at least one operable coronary narrowing. Patients were randomly assigned to medical or surgical therapy and followed for a mean interval of nearly six years. Annual mortality rates in the surgical and medical groups were 1.1 percent and 1.6 percent respectively. This difference is not significant. The investigators concluded that patients similar to those enrolled in the CASS study can safely defer bypass surgery.

Question: Does bypass surgery save lives?

Answer: It has been clearly demonstrated that coronary artery bypass graft surgery prolongs life in patients with narrowing of the left main coronary artery. This is the most dangerous coronary lesion.

Coronary bypass graft surgery relieves chest pain in a large proportion of those afflicted with frequent, severe attacks of angina or chest pain. For this group of patients, the question of prolonged survival is moot, since relief of chest pain by palliative surgery is overriding.

Question: Is there a difference in mortality between those who were treated with drugs and those who were treated with surgery?

Answer: Coronary bypass graft surgery in those with mild symptoms does not appear to prolong an already excellent survival outlook in patients treated medically. In addition, bypass grafts do begin to close in a rather large proportion of patients (40 percent) after ten years. The second operation is more risky and technically more difficult. Thus, in mildly symptomatic patients, CASS investigators recommend medical therapy until symptoms dictate surgery.

Question: What studies and/or guidelines do you plan as the result of your coronary artery surgery study?

Answer: The patients involved in the study will be followed for an additional five years, bringing the mean follow-up interval to nearly eleven years. This long-term follow-up experience will be very important. The similarity in survival rates between the two groups may change over this period. The Institute has vigorously disseminated the CASS results. The medical community is in the process of discussing and evaluating CASS. It is quite likely indications for bypass will be refined as a result of the study.

Question: What about laser treatment to break through blocked arteries--doesn't this hold some promise? Would it be any better than running a tiny inflated balloon through the artery?

Answer: Laser vaporization of arterial narrowing is a promising therapy which may ultimately lead to more effective means of treating arterial disease. This therapy is in its infancy. There is no consensus as to the most effective laser source, energy levels, and dangers inherent in this procedure.

Application in the most commonly affected and most important arteries, the coronaries, is particularly difficult because perforation of the artery is life threatening. The long-term sequelae given successful opening of the blocked artery are unknown. For example, the artery might close again in a short period.

The cardiology community is actively investigating laser angioplasty. It is believed that it will take three to five years to begin answering the questions surrounding this therapy.

## ARTIFICIAL HEART

Question: Last year you told us that as a clinical experiment the artificial heart case of Dr. Barney Clark "was a success in that the patient's life was extended beyond what had been anticipated and the device functioned well." A year later do you still feel the same way about this procedure -- and do you know of any plans for further experimentation with the artificial heart?

Answer: We feel that Dr. Clark's experience with an air-driven artificial heart has helped to establish the feasibility of a mechanical device to perform both the blood pressure and blood flow functions of the natural heart but leaves unanswered the question of its clinical usefulness. Not much more could be expected from this pioneering investigation, and nothing more was achieved. Clinical usefulness will be determined three to five years from now when totally implantable systems are available for clinical evaluation.

We believe there will be further experimentation with the air-driven artificial heart. In addition to the University of Utah, two or three other research teams are petitioning the Food and Drug Administration (FDA) for Investigational Device Exemptions (IDEs) to use the air-driven artificial heart as a bridge to cardiac transplantation. Approximately one-third of the transplant candidates die of circulatory failure before surgery. These patients may benefit from a period of circulatory support of a few weeks or months while a suitable donor is located.

The questions posed by the Food and Drug Administration (FDA) to the University of Utah and Kolff Medical appear to be routine and should be answerable. We would still envision FDA approval in the foreseeable future. After the FDA acts , approval must be sought from the University of Utah Adminstration before beginning the selection process for a second candidate.

Question: How much is the Heart Institute spending on this research at present -- and how much do you contemplate spending in fiscal 1985? What will the money be used for?

Answer: The National Heart, Lung, and Blood Institute (NHLBI) is supporting $9 million on our targeted program for the development of an implantable electrically powered ventricular assist device with a demonstrated two-year reliability. In addition, the Institute is supporting an equal amount of activity in related grants studying biomaterials ($6 million) and artificial heart ($3 million).

In FY 1985, we contemplate supporting between $8 and $9 million in our targeted program. The major portion of this support will be directed at our device readiness program which will begin in the summer of 1984. The purpose of these studies is to develop testing guidelines and obtain reliability data which will insure the safety of these devices before they are implanted in human patients. Ten or twelve systems ($40,000 each) will be placed on simultaneous test in vitro to obtain statistical data, and the performance of another six systems will be studied in animals. The most promising concepts will be tested.

Question: With the advent of better drugs that prevent organ rejections, why not opt for more heart transplantation rather than use of the artificial heart?

Answer: Cyclosporin has certainly shown promise for controlling organ rejection. However, it is not without side effects (renal dysfunction and arterial hypertension), and some patients cannot be treated with the drug. Also, the chronic effects of using cyclosporin are still unknown.

The results from heart transplants are currently much better than can be expected from a mechanical device, but the clinical usefulness of cardiac transplantation is still limited by the lack of donor organs and the total cost of the procedure.

Question: What is the availability of donor heart for transplantation?

Answer: The National Heart Transplantation Study is currently addressing the issue of availability of organs, and their preliminary estimates indicate there are approximately 1,500 donor hearts available each year. Some experts estimate that there may be as many or 10 times as many donors if it were possible to harvest all available organs. With high public interest and the development of the American Transplantation Council, it is possible that the number of organs might increase. It is unlikely that the actual donor pool size will change by more than 1,500 to 3,000 because donor organs are preferred from donors under 35 years of age and deaths from trauma and drunk driving appear to be falling. Probably about 200 heart transplants will be performed in the U.S. during 1984.

## CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Question: Chronic obstructive pulmonary disease is reported to be the fastest rising major cause of death in the United States. What accounts for this and what progress are you making in efforts to combat it?

Answer: Chronic Obstructive Pulmonary Disease (COPD) is the fastest rising cause of death in this country because of the rapid rise in cigarette smoking earlier this century. Since smoking is the overwhelming risk factor for COPD and takes over 30 years to result in death, the population that began to smoke before, during, and shortly after World War II is now being seen in the health care system with evidence of COPD, with many dying of the disease.

At present, the only way to combat COPD is to prevent it. There is no known cure for COPD, but in almost all cases the disease can be prevented by abstinence from smoking cigarettes. The Institute is therefore supporting research on methods of motivating adolescents not to smoke, providing smoking cessation counseling in the health care system, conducting smoking cessation programs in the worksite, and providing smokers educational materials to quit on their own. Other research centers on understanding the etiology of the disease and its processes. Factors being investigated include the role of occupational and genetic factors, airway hypersensitivity, the effects of previous airway diseases such as bronchiolitis in childhood, repeated viral or bacterial respiratory tract infections, and involuntary smoke exposure (passive smoking) during early infancy and childhood. Molecular and cellular mechanisms for injury and repair of lung tissue are also being investigated.

Question: What role can long-term screening for abnormalities in lung function play in detecting this disease?

Answer: Screening could help detect mild airway obstruction in high risk individuals such as asymptomatic smokers; and cessation of smoking by these individuals might slow or prevent the onset of disabling disease. Currently, there are a number of reliable techniques for detecting Chronic Obstructive Pulmonary Disease. However, by the time a definite diagnosis of the disease is made on the basis of these techniques, some irreversible lung damage has occurred. Population studies indicate that lung function declines slowly with age in healthy nonsmokers; in smokers, however, deterioration of lung function tends to be much more rapid. If a smoker with mild Chronic Obstructive Pulmonary Disease stops smoking, the rate at which lung function deteriorates returns to normal. But some permanent damage has probably occurred by this time and it is likely that pulmonary function will never completely return to normal.

Extremely sensitive tests which evaluate small airways function are capable of detecting abnormalities in about one-third of cigarette smokers. The functional impairment detected by these tests can be reversed if the subjects stop smoking. These findings support the concept that the damage may be reversible at some early point in the disease. If at that stage a susceptible person can be identified and convinced to give up cigarettes, the later phases of this inevitable progressive illness can be prevented. It has been suggested that these sensitive tests of small airway function might help identify which smokers would have a high risk of developing severe airway obstruction if they continue to smoke. Although a number of tests can now detect abnormalities in the small airways, it is impossible to predict which individuals with these abnormalities will go on to develop symptomatic obstructive airways disease. Prospective studies involving these tests may be able to identify useful early predictors of disease.

Question: Should general practitioners do more screening for the disease than they do at present? What guidance are you providing them?

Answer: At present more information is desirable before the Institute provides guidance concerning large scale screening. Smokers experience an accelerated decline in pulmonary function, and evidence from epidemiological studies indicates that after cessation of smoking the rate of decline of pulmonary function returns to normal. Another presumed risk factor for accelerated decline in pulmonary function is the presence of hyperreactive airways. It is possible that if the hyperreactive airways are kept non-reactive by pharmacological means over a period of years, the expected abnormal decline may be lessened. This effect may be enhanced by the cessation of cigarette smoking. Although the evidence is strong that smoking and hyperreactive airways are risk factors for Chronic Obstructive Pulmonary Disease, it has not yet been demonstrated that removal of risk factors at a stage of mild dysfunction will effectively modify the course of the disease. In FY 1984, the Institute will begin a major clinical study to determine if the downhill course of the disease can be prevented when an individual quits smoking, and if those with hyperreactive airways begin a regimen of bronchodilator drug. In the proposed study, individuals who are identified as having mild abnormalities in pulmonary function will be randomized into a "special care" group or a "usual care" group. Subjects will be followed for five years to determine the effects on decline in pulmonary function and subsequent respiratory illness. If the study indicated that smoking cessation counseling, the administration of bronchodilators, and diligent follow-up can slow the progression of chronic obstructive airways disease, then more screening for Chronic Obstructive Pulmonary Disease is important and necessary.

HEMOPHILIA GENE

Question: We understand that some progress has been made in regard to finding the gene involved in hemophilia. Please bring us up-to-date on this?

Answer: Although there have not yet been any publications in the scientific literature, at least two genetic engineering companies have released announcements to the press that they have isolated the gene for factor VIII, the clotting factor that is missing or defective in classical hemophilia. The identification of what is most likely a large fragment of the complete gene for factor VIII represents a major scientific advance. Most knowledgeable investigators believe it is just a matter of time and application of standard techniques in molecular genetics until the entire gene is isolated and characterized.

The next step for in vitro production of factor VIII will be to find a system in which it can be expressed in an active form. Estimates of the timetable to achieve this goal range from one to five years. Factor VIII is a very large protein whose structure-function relationships have not been fully elucidated. It requires specific conformational features and the addition of sugar residues for activity and it is extremely sensitive to enzymatic digestion. Therefore, it is quite different from proteins that have thus far been produced by recombinant DNA technology, and the real challenge is to find the appropriate cells and conditions under which to obtain a biologically active protein. This is an area of intensive investigation, primarily in the private sector, and the results of this research have far reaching implications for the treatment of hemophilia, for understanding the genetics of the disease, and for improved genetic counselling. In addition to this research, other laboratories have isolated and sequenced the gene for factor IX, the clotting factor involved in hemophilia B. Comparison of the normal gene with the abnormal factor IX gene from hemophilia B patients has already provided scientists with new information as to the defect in this disease.

Question: What effect will the discovery have on treatment of the disease?

Answer: The availability of an "artificially produced" factor VIII could substantially change the treatment of hemophilia by making available a product with fewer adverse side effects than those associated with products currently on the market. Whether this material would be less expensive than current products is unknown, and will depend to a large extent on the type of cell necessary to produce an active protein and the cost of expressing it.

Even before a recombinant product is available for treatment, however, the results of research on the factor VIII gene itself will have other applications related to genetic counselling. Preliminary findings indicate that there are differences (polymorphisms) in the factor VIII gene which can be applied to identification of carriers of hemophilia. Thus it may be possible to distinguish between those women who are at risk of bearing a son with mild hemophilia and those who carry the gene for a more severe form. This advance in genetic counselling applies to both classical hemophilia and hemophilia B.

Question: Will recombinant DNA techniques be used to produce the factor involved and will this eliminate the danger of transmitting AIDS to hemophiliacs?

Answer: Yes, recombinant DNA technology could be utilized to produce factor VIII. Currently, the replacement factor is obtained from human plasma and contains other plasma proteins as well as blood-borne viruses. Its availability is also dependent upon a supply of blood or plasma, either from volunteer donors or from commercial plasma collection centers. Recombinant factor VIII would have the advantage of being virus-free, more highly purified, and not dependent upon a blood supply. It would eliminate the problem of non-A non-B hepatitis virus(es), which is currently present in virtually all commercially-produced concentrates. If AIDS is indeed caused by a virus carried in the blood, it would also eliminate this danger.

## HYPERTENSION

Question: Hypertension is still the silent killer. While we seem to be doing better in detecting and treating hypertension, we no doubt have a long way to go. Please bring us up-to-date on your efforts which I gather have been spearheaded by your National High Blood Pressure Education program.

Answer: The National High Blood Pressure Education Program of the National Heart, Lung and Blood Institute has recently completed the coordination and preparation of the 1984 Report of the Joint National Committee on Detection Evaluation and Treatment of High Blood Pressure. Like its predecessors this report, written by a panel of national experts from a variety of organizations including the American Heart Association and the American Medical Association, presents the most up-to-date knowledge on key facets of hypertension. These include definitions and prevalence of hypertension, screening algorithms for high blood pressure, diagnostic strategies, non-pharmacological and pharmacological treatment modalities, and community programs aimed at population based approaches to the control of high blood pressure. The press conference heralding the release of this report is scheduled for May 1, 1984, and the official report will appear in the May 1984 issue of the Archives of Internal Medicine.

Question: To what degree have detection and control of high blood pressure contributed to the falling rates of cardiovascular disease?

Answer: Epidemiological surveillance data over the past 10 years have demonstrated dramatic falls in cardiovascular disease mortality and morbidity, especially coronary heart disease and stroke. Several factors are probably responsible for these declining rates including change in the American diet, increased exercise and the control of high blood pressure. Unfortunately, precise data that would allow us to determine the exact contribution made by each of these factors to the decline in the morbidity and mortality rates are not available. There is a general consensus within the scientific community that the control of high blood pressure has contributed significantly to these decreased rates, especially to the decline in the incidence of stroke.

Question: Where do you stand on treatment of mild hypertension -- do you favor use of drugs or other means to effect treatment? Why?

Answer: Patients with mild hypertension, defined as diastolic pressures persistently in the range of 90-104 mm Hg, are at increased risk for developing premature morbidity and mortality. The risk within this large group of patients (approximately 70% of all hypertensive patients) is not uniformly distributed. That is to say, not everyone in this group has a uniformly poor or a uniformly good prognosis. For example, the higher the pressure is within this range of 90-104 mm Hg, the greater is the risk. The presence of additional risk factors such as cigarette smoking or high cholesterol raises the risk. Likewise, the presence of target organ damage - pathological changes in the heart, kidney or blood vessels consequent to elevated blood pressure - increases the risk for developing premature cardiovascular disease. Therefore, careful monitoring and nonpharmacologic approaches are recommended for the management of all patients with mild hypertension. If this approach fails and the diastolic blood pressure is persistently above 95 mm Hg, especially if there are concurrent risk factors, then serious consideration should be given to drug treatment. In the group whose diastolic blood pressures are 90-94 mm Hg management is somewhat controversial. Some physicians definitely treat this group of patients with drugs when nonpharmacologic modalities have not been successful. Other physicians tend to delay treating these patients with drugs, especially when there are no other concurrent risk factors or evidence of target organ damage. The 1984 Report of the Joint National Committee on Detection Evaluation and Treatment of High Blood Pressure suggests that careful monitoring and nonpharmacologic approaches be used for everybody with mild hypertension; that drugs be considered for patients with diastolic pressures greater than 95 mm Hg and in whom nonpharmacologic approaches have not been successful; and that treatment be individualized and use of drugs be left to the discretion of the attending physician for patients with diastolic blood pressures in the range of 90-94 mm Hg.

Question: What guidance are you giving doctors on treating hypertension?

Answer: Precise recommendations on the treatment of hypertension are contained in the 1984 Report of the Joint National Committee on Detection Evaluation an Treatment of High Blood Pressure. Briefly the recommendations suggest careful monitoring the patients' blood pressures, judicious use of diagnostic tests and non-pharmacological treatment of all patients with hypertension, including mild, moderate, severe and isolated systolic hypertension. Drugs are to be used with great care in all hypertensive patients. In patients with mild hypertension, use of drugs should be considered, but is not necessarily recommended, in patients with pressures in the 95-104 mm Hg range when nonpharmacological treatment has failed. The attending physician is best able to decide on the use of drugs for patients with pressures in the 90-94 mm Hg range when nonpharmacological treatment has failed.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### SMOKING AND HEALTH

Question: I notice that the National Heart, Lung, and Blood Institute spends a substantial amount of money on programs that are intended to motivate people to stop smoking. For example, over $160,000 is being spent to establish the feasibility of developing, implementing, and evaluating a self-help smoking cessation program for employees of the University of Alabama in Birmingham. Can you tell us how much you are currently spending in this area and how much you plan to spend next year?

Answer: For research on smoking cessation and health, the Institute will spend approximately $7.3 million in FY 1984 and approximately $7.5 million in FY 1985.

In the area of intervention and education, we have several activities underway which will result in additional monies being spent in FY 1985. We will be developing new smoking educational projects for use in the physician's office and at the worksite. We will be contracting for support in this area, particularly in establishing a network of medical associations, public health groups, voluntary organizations and business and labor organizations through which we will work in trying to help patients, employees and other citizens give up the smoking habit. In addition, we will be giving further distribution to those publications and audio-visuals which have been reported as useful tools by practitioners in the field. The estimated cost for these anti-smoking educational activities is $500,000 in FY 1985.

Question: Do you have any long-term goals for this particular effort? To put it another way, how will you know when to reduce funding in this area?

Answer: The long-term goal of our smoking program is to help smokers quit and to assist in persuading young people not to start. Statistics show the proportion of smokers declined steadily from 42.8 percent in 1966 to 33 percent in 1980. This trend indicates that efforts since the 1964 Surgeon General's report to decrease the number of smokers is having a positive effect. However, one-third of the population continues to smoke and research is still needed to determine the best ways to persuade smokers to quit and not start again. This research will focus on ways to intervene in disease processes that are related to smoking; to assess the effectiveness of smoking cessation methods; and to better understand the effects of smoke on non-smokers.

In pursuing its long-term goal the Institute will work with many organizations in the public and private sectors. The Institute will continue to develop educational methods and projects which can be adopted by private organizations such as the American Lung Association and the American Heart Association. Funding in this area will be reduced when smoking is no longer a factor in the development of cardiovascular and pulmonary diseases.

Question: How does your smoking research program interact with the smoking and health program funded by the Office of the Assistant Secretary for Health?

Answer: The Institute interacts with the Office of Smoking and Health (OSH) in three ways. First, the Institute uses the publications of OSH to keep up with the state of the science and to develop initiatives for research programs. The annual Surgeon General's report is used as a definitive document on smoking research; the Bibliography on Smoking and Health is also a useful document for the community conducting smoking research. Second, the Institute is working closely with OSH to provide a recommended outline and potential authors for the 1984 Surgeon General's Report on Smoking and Chronic Obstructive Pulmonary Disease. Third, the Institute participates with OSH in the Interagency Technical Committee on Smoking and Health, in which representatives of several Federal agencies share information on current and planned programs on smoking and health. In this forum, research findings and planned programs are presented and discussed. Group comments are often incorporated into our programs. The Institute will continue to maintain a close working relationship with that office in order to avoid unnecessary duplication and enhance cooperation.

## SUPPLIES AND MATERIALS

Question: Dr. Lenfant, I note that despite a substantial Congressional increase in your fiscal year 1984 budget submission you have been forced to cut back on supplies and materials expenditures from an initial 1984 estimate of $10,274,000 to a current 1984 estimate of $8,688,000. Please tell us where you made this reduction and how it has affected your operations?

Answer: The original estimate for FY 1984 of $10,274,000 included funds for drugs used in clinical trials supported by the Institute. Because of the completion of these trials and the Institute's successful efforts to have drugs for other studies donated, these funds were not required. In developing the FY 1985 budget, the Institute revised its FY 1984 estimate to reflect this latest information.

## OTHER SERVICES

Question: On page 100 of your justifications you list a subcategory of expenditures termed "other". Please tell us what types of expenditures this designation covers and explain why your initial 1984 estimate of $13,553,000 has been reduced to a current estimate of $11,813,000 despite a substantial add-on to your budget request.

Answer: The other services category includes a wide variety of purchased services including office and laboratory equipment repair, data processing services, staff training, photography and graphic arts services, consulting and professional services, fee-for-service alterations and maintenance services, program evaluation assessments and contracts that support our public education program. The initial 1984 estimate of $13,553,000 you reference was reduced in the 1984 amended President's Budget to $13,182,000. The Institute reduced this amount further when developing the

FY 1985 budget to reflect the latest information available. Savings have been achieved in services funded through the NIH service and supply fund, particularly rate reductions for Division of Computer Research and Technology data processing services. Other savings have occurred in consulting services and research support contracts, including professional service contracts.

## TREATMENT OF MILD HYPERTENSION

Question: Dr. Brandt, a physician friend of mine has written me about an advisory you signed last November regarding the treatment of mild hypertension. I'd like to discuss this advisory with you today because I think it raises some interesting questions concerning the overuse of drug therapies to deal with health problems. The advisory stated that pharmacologic treatment should be considered when other treatments are not effective in maintaining control of mild hypertension.

First let me refer to the advisory's citation of a Veterans Administration study conducted by Dr. Freis. The advisory says "the study reported convincing evidence from controlled trials that drug treatment of male patients with moderate hypertension helped prevent stroke, renal failure and heart failure."

I'm surprised that you cited that study because it did not recommend the use of drugs for mild hypertension, which is the subject of the directive. Since Dr. Freis has specifically stated that no benefit from drugs was found in mild hypertension, why was the Freis study cited?

Answer: The Veterans Administration Study is a landmark study which included a broad spectrum of hypertensive patients and was then followed in time by the Australian trial, the HDFP and MRFIT. Even though it did not have enough patients to test the question of benefit in the 90-104 group with sufficient power, the trend was in the same direction of benefit as the overall VA study, the Australian Trial findings and the Hypertension Detection and Follow-up Program. Morbid events were more than 50 percent higher in the placebo group than in the treatment group but this large percentage difference did not reach statistical significance. It is not appropriate, when numbers are so small, and the power of the test is very low, to equate a substantial but statistically non-significant difference with "no difference". Though the finding could have occurred by chance in that subgroup of mild hypertensives in the VA trial, the trend was so consistent with overall significant study findings that it seems likely there was some difference.

Question: The advisory goes on to state that a subgroup analysis of the Multiple Risk Factor Intervention Trial (MRFIT) -- another major blood pressure clinical trial -- included an observation of comparatively higher mortality among those mild hypertensives who had both ECG abnormalities at baseline and were given drug therapy. In fact didn't that study find a 66 percent higher death rate in mild hypertensive subjects who received drug therapy?

Answer: There was approximately a 65 percent higher coronary heart disease (CHD) death rate in Special Intervention (SI) hypertensive individuals with resting ECG abnormalities than in the

Usual Care (UC) in the same subgroup. The numbers of CHD deaths were small (36 vs 21); hence the percent difference is not necessarily a stable estimate. Mortality in hypertensive SI participants was found to be associated with the combined factors of resting ECG abnormality and diuretic use. This finding was not found in UC even though many of them were also receiving diuretic therapy, generally at lower dose levels.

Question: Why does the directive refer to this finding as "creating confusion"? It seems pretty straightforward to me.

Answer: The finding in MRFIT of a higher CHD mortality rate in the Special Intervention (SI) subgroup with baseline resting ECG abnormalities than in the Usual Care (UC) subgroup with resting ECG abnormalities is based on a subgroup analysis with low statistical power. In fact, the difference does not reach statistical significance, i.e., it could have occurred by chance. It is, however, significantly different from the results in hypertensive persons in MRFIT without resting ECG abnormalities at baseline where CHD mortality was less among SI than among UC. The UC mortality rate for the hypertensives with resting ECG abnormalities was unusually low, perhaps by chance.

Because of the special intake criteria for MRFIT, these subgroups with ECG abnormalities are difficult to compare with similar subgroups from other studies. The comparison in MRFIT is between two drug-treated groups. In the SI group, mortality was associated with having resting ECG abnormalities at baseline and being placed on diuretic treatment; this association was not found in the UC group, though many in this subgroup were also on diuretic therapy, generally at lower dosage.

Question: Dr. Krishan, who chairs the Heart, Lung, and Blood Institute's Joint Committee on Detection, Evaluation and Treatment of High Blood Pressure has stated "I'm very concerned there may be a rush to put young people with diastolic pressure of 90 to 95 mm mercury on a lifetime drug regimen. I think that's unconscionable and unnecessary." Doesn't your directive promote the rush to drug therapy that Dr. Krishan warned about?

Answer: The directive and 1980 Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure should not be interpreted to support a "rush to drug therapy" for elevations of diastolic blood pressure of 90 to 95 mm Hg. These documents recommend that for the broader range of mild hypertension, i.e., diastolic 90-104 mm Hg, drug therapy has been shown to be beneficial and should be considered when non-pharmacologic treatment is not effective in controlling the blood pressure. There has not been a trial that studied only the 90 to 95 mm Hg level of blood pressure, and no trial has had enough patients in that specific category to unequivocally establish whether they benefit with regard to reduction in mortality and/or morbidity from any specific kind of treatment, drug or non-pharmacologic. The trends in total mortality in the Hypertension Detection and Follow-up Program in the 90 to 95 mm group were beneficial; in MRFIT the trend was not beneficial. One final point, none of the recommendations suggest that doctors should treat persons with mild elevation of blood pressure based upon only one reading.

Question: Dr. Kaplan stated in an article that appeared in the Annals of Internal Medicine last year that the benefits of drug therapy have not been proven in cases with a diastolic pressure below 100, and that these patients should be given non-drug therapies. Dr. Stammler, one of the architects of the MRFIT study, has said that the lesson of that study "is to treat hypertensives non-pharmaceutically, using lifestyle interventions". Given these negative comments, why do you downplay non-pharmacological treatment in the directive and recommend the use of drugs, even in the subgroups with abnormal resting ECG's?

Answer: The Hypertension Detection and Follow-up Program (HDFP), supported by this Institute, and another trial, the Australian Therapeutic Trial in Mild Hypertension, showed benefit or beneficial trends in their pharmacologic treatment groups extending below 100 mm Hg.

However, the directive should not be viewed as downplaying non-pharmacologic therapy; it explicitly supports this therapy as first line therapy in persons with mild elevations of blood pressure. Nevertheless, non-pharmacologic therapy has not always been effective in lowering blood pressure in persons with mildly elevated blood pressure. For these individuals, in whom non-pharmacologic therapy has not been successful, and who, because of their elevated blood pressure, remain at increased risk of coronary heart disease and other complications, the data from hypertension trials are adequate to support consideration of drug therapy. The Multiple Risk Factor Intervention Trial data on persons with baseline resting ECG abnormalities and hypertension do not cast doubt upon the benefit of all antihypertensive drugs in this subgroup; only diuretic use in this subgroup in MRFIT is associated with the adverse finding. Certainly the data for diuretics cannot be reviewed as definitive. Further research is needed to understand the meaning of these complex findings.

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## QUESTION SUBMITTED BY SENATOR DANIEL K. INOUYE

### PREVENTION

Question: For some time the Committee has been very interested in your pioneering efforts in Prevention. Would you please provide us with a report on what you have been able to do in this area?

Answer: Our prevention activities--both in the area of research and in the area of intervention, including professional and public education--continue to receive a high priority at the Institute. Within the past few months, we released the findings of the Lipid Research Clinics Coronary Primary Prevention Trial which represented one of our major research endeavors in the area of primary prevention. This study has given us conclusive evidence, for the first time that lowering elevated cholesterol levels in humans can reduce the incidence of heart disease and heart disease deaths. Some scientists have estimated that if we apply the lessons of this major trial, we may be able to prevent as many an 100,000 deaths a year. Whether or not that projection becomes reality depends on many factors that we will be actively addressing. Our plans for building upon the findings of this landmark study are threefold. First, through continued research we will pursue the answers to more precise questions that were identified in this study. Second, we will attempt to develop consensus and guidelines regarding these findings through two major meetings this year with the scientific and medical community. Third, we will use that guidance to help us develop a major education effort which will be directed at physicians, other health professionals and the general public. Our experience to date in the area of prevention gives us confidence that this new effort will result in a positive contribution to the public health.

Congress mandated the Institute to become active in the area of information and education in 1972. Our major educational effort since that time has been in the area of high blood pressure control. Since that effort began, the number of physicians vigorously treating high blood pressure has increased significantly and the level of awareness and understanding among the public has increased considerably. In addition, the number of hypertensives who have their condition under control has doubled and hypertensive related deaths has decreased dramatically. High blood pressure is the primary cause of stroke and the mortality rate for stroke has decreased by well over 40 percent during the past 10 years. We have learned lessons from the high blood pressure experience that we are applying to other efforts. One, there must be a scientific base in order for the messages to be credible. Two, if a major educational effort is to reach as many people as possible, there must be a partnership formed with medical, public health, voluntary, labor and business groups and organizations. The Federal Government cannot and should not do the job alone. And, three, the effort must be sustained if the benefit is to be continued.

We will continue to act in the role of catalyst, as a source of credible information, as an originator of educational messages and as a partner with many others concerned with disease prevention not only in the area of high blood pressure but in cholesterol reduction, smoking cessation and in other areas related to heart, lung, and blood diseases.

## NATIONAL INSTITUTE OF DENTAL RESEARCH

## STATEMENT OF DR. HARALD LÖE, DIRECTOR

## ACCOMPANIED BY DR. JOHN GOGGINS, DEPUTY DIRECTOR

### BUDGET REQUEST

Senator WEICKER. Next we'll hear from the National Institute of Dental Research.

The fiscal year 1985 budget request for the Institute is $91 million, an increase of almost $3 million over the 1984 level.

Here to present the new budget is Dr. Harald Löe. We welcome you, Dr. Löe and proceed.

Dr. LÖE: I have with me today, the Deputy Director of the NIDR, Dr. John Goggins. In addition to my written statement, I would like to report to you that the NIDR's research plan, which is subtitled "Challenges for the eighties," is now completed. The plan describes significant accomplishments and resulting benefits to society and gives testimony to the fact that dental research has become mainstream biomedical research. The plan spells out opportunities and leads in research that we think demand pursuit and underscores the potential for dental medicine to become primarily a preventive rather than treatment-oriented discipline.

Dental research continues to address problems of the major dental and oral diseases. We are not content to stand on the record that tooth decay rates have been cut in half and that a third of America's children are caries free, but we are charging ahead with research aimed at the complete elimination of tooth decay.

As the number of adults and elderly who have been able to preserve their teeth grows, periodontal diseases are becoming an increasing public health problem. A new form of decay, root surface caries, is also being seen. To assess these serious disease problems, we are planning a national survey of oral health in adults and the elderly to begin in 1985. There is much excitement in that research today, not only because of recent achievements, but also because of the challenges and the potential for progress that we see.

### PREPARED STATEMENT

I will be pleased to answer any questions that you have.

[The statement follows:]

## STATEMENT OF DR. HARALD LÖE

I am delighted to appear before you today as I begin my second year as Director of the National Institute of Dental Research. 1983 was an exciting and productive year, culminating in the publication of the Institute's Long-Range Research Plan, FY 1985-1989, Challenges for the Eighties. The Plan was the joint effort of experts within and outside the government, impelled by the mood of excitement we see in dentistry today as the profession moves rapidly ahead to a new stage. The Plan will serve as the Institute's blueprint for the future, assessing needs and scientific opportunities in the light of NIDR resources and potential. Ultimately we look forward to a time when not just young people, but the middle-aged and elderly need never lose a tooth to disease; a time when the practice of dentistry is largely one of prevention. To achieve those goals, we are calling for a closer partnership with the academic, professional and business communities. We urge a more rapid transfer of science and technology from research to dental practice to general knowledge and will draw upon the social and behavioral sciences to further those ends. We will strive to maintain the excellence of our own broad-based intramural research program. And we emphasize the importance of research training. We are working to establish mechanisms to augment the supply of dentist-scientists, clinical scholars whose dental training is combined with research experience in biomedical fields so that the pace of oral health research can proceed and even accelerate.

That pace has been noteworthy in the past year. Important findings include the isolation of the gene that controls production of a major constituent of tooth enamel, the hardest substance in the body. Now, using gene cloning techniques, we have the potential of filling cavities with materials that will harden into a substance virtually identical with natural tooth enamel. Other significant advances include evidence that the antibiotic tetracycline plays a dual role in treating severe gum disease. Not only does the drug attack bacteria implicated in the disease, but it also reduces elevated levels of tissue collagenase, an enzyme that destroys collagen--the basic building block of the connective tissues, ligaments and bones that support teeth. Still a third significant finding is the identification of cell surface receptors on certain cancer cells that aid in the spread of cancer.

This knowledge is spurring research to develop means of deactivating the receptors to improve defenses against invasive cancer.

These findings illustrate features of dental research not always appreciated. One is that dental investigators contribute innovative ideas and methods within the mainstream of biomedical research, making use of such versatile tools as recombinant DNA and monoclonal antibody technology. A second feature is that in the course of investigating oral tissues, dental scientists explore mechanisms of cell function and disease processes common to other body tissues.

Research on herpes virus infections underscores that second feature. At least a third of the world's population suffers painful, often recurrent cold sores or fever blisters. These ulcers on the lips or inside the mouth are caused by herpes simplex viruses, members of a group that includes the viruses that cause shingles and genital herpes as well as an agent associated with a human cancer. After initial infection, herpes viruses can be harbored in the nervous system where they may lie dormant or become reactivated to cause repeated episodes of disease. NIDR investigators have established that in some cases segments of the viral DNA become incorporated into the host cell's DNA. Related studies have shown that some of these host DNA sequences have been identified with human "cancer" genes--bits of DNA found in all cells that may once have served some useful function. Viral infection offers a possible mechanism by which these sequences of host DNA could be expressed, leading to destructive changes.

Work continues on developing effective herpes treatments and means of preventing infection by vaccines. Clinical trials using weakened electric currents (iontophoresis) to propel the antiviral drugs vidarabine phosphate (ARA-AMP) and acyclovir (ACV) have been impressive. With ARA-AMP, 8 out of 10 subjects with oral herpes lesions were virus free after 48 hours. Use of either drug reduced lesion size and pain and shortened healing times. Phase III trials--double blind human studies--have been started.

Infections of the oral cavity and host response mechanisms are a major focus of NIDR research and have been since the pivotal discoveries that the two most common and costly oral conditions--tooth decay (dental caries) and gum diseases (periodontal diseases) are bacterial infections.

NIDR's 1979-1980 survey established that over the decade, the number of youngsters ages 5-17 who were completely caries free rose to about one third, while the evidence of decay in the remainder declined by about 30%. These impressive reductions are saving the American public $2 billion a year in dental bills and have largely been attributed to the effectiveness of fluoride in increasing the tooth's resistance to decay and in aiding in the repair of tooth enamel. We can now add to the arsenal of caries-preventive weapons adhesive sealants. These are synthetic resins applied to the chewing surfaces of posterior teeth to seal out decay. The sealants cover the deep crevices of teeth, areas vulnerable to bacteria where fluoride is less effective. NIDR research has led to improved sealant formulations and easier methods of application. Even so, we have documented evidence that early sealants are still holding up seven years after application. An NIH Consensus Development Conference held last fall unanimously concluded that the use of sealants is a safe and effective means of preventing coronal caries (decay in the crowns of teeth) that complements the use of fluoride.

The battle against caries is not over. We are concerned about high-risk groups such as the handicapped or disease-compromised patients. We are also concerned about changing patterns of tooth decay. A new generation of adults is emerging who have retained nearly all their teeth. We need to determine the prevalence of new coronal caries in these people as well as recurrent caries around existing restorations. As gums recede, tooth roots are exposed to the oral cavity and preliminary studies suggest that root caries may be an emerging problem. Accordingly, an epidemiological survey assessing adult oral health status in caries and in gum diseases is planned for the coming year. Caries research will continue to improve means of prevention and therapy targeted to specific populations.

Caries vaccine studies are proceeding apace. A safe and effective oral vaccine, possibly given to infants in the first year of life, could stimulate the immature immune system to produce antibodies to the bacterium Streptococcus mutans, considered the major cause of coronal caries. Importantly, antibodies produced by the oral-gastric route circulate to the oral tissues where they are released in saliva, thus putting the anticaries ammunition where it is most needed.

We are now ready to move on to larger-scale clinical trials with a fluoride slow-release device, a small tooth-sized implant that would provide a constant low level of fluoride in the mouth to protect individuals at high risk of developing tooth decay. When restorations are necessary, the NIDR continues to support the development of materials and methods that are cosmetically superior, durable, less costly, less destructive of tooth substances and more comfortable. The trend toward bonding natural-looking composite materials to the enamel of anterior teeth is well underway. Today we can report encouraging results with new techniques that will allow bonding tooth-colored composites to the dentin underlying surface enamel. In the future a combination of stronger formulations and new methods should permit bonding composites to posterior teeth that are normally subject to greater stress and wear.

While we will not relax our vigilance to press on to total eradication of caries, the NIDR expects to increase efforts to eradicate the periodontal diseases, the major causes of tooth loss in adults. These diseases range from mild reversible gingivitis with symptoms of inflamed and bleeding gums to advanced periodontitis in which deep bacteria-filled pockets form around affected teeth leading to tooth mobility and loss.

The periodontal diseases present a challenging array of complexity that has stimulated research. Different periodontal diseases appear to be associated with different microorganisms in plaque, the film of bacteria and their products that builds up on teeth and gums. The body's response to periodontal disease bacteria is also complex, involving immune factors that in themselves contribute to tissue destruction. The diseases are usually insidious in onset and often exhibit periods of quiescence followed by periods of disease activity. NIDR diagnostic systems scientists are developing digitized tomographic techniques to enhance x-ray analysis, in order to detect more subtle signs of disease activity or progression.

Today we can identify the major pathogens associated with chronic periodontitis in adults--the most common form of destructive gum disease--and localized juvenile periodontitis, a rapidly destructive periodontal disease that affects young people. Scrupulous oral hygiene and periodic dental visits to remove hardened deposits and plaque from areas not accessible to self-care can prevent periodontal diseases and reverse gingivitis. Surgery to permit plaque removal from deep pockets, followed by scrupulous oral hygiene, can arrest more advanced disease and lead to tissue repair. These methods are not ideal, however. Through research, the NIDR would like to bring to the American people easier, even more effective means of periodontal disease prevention. We are, therefore, increasing our efforts to develop new chemical therapies--safe and effective antimicrobials to be used as mouthwashes to destroy plaque. As well, we are making strides in elucidating the behavior of the pathogenic bacteria and the body's immune system.

I have enlarged upon a few major oral health problems in order to show the extent of NIDR research. I would like to conclude by touching briefly on a variety of NIDR research activities that address other important health questions.

1983 saw the inauguration of NIDR's new Pain Research Unit in the Ambulatory Care Research Facility of the NIH Clinical Center. NIDR investigators are among world leaders in pain research, adding to the basic fund of information on neuroanatomical pathways and chemicals involved in the transmission and suppression of pain sensations. Research at the Unit is not limited to orofacial pain but concerns diagnosis, measurement and treatment for many acute and chronic pain conditions. Allied work among our behavioral scientists is revealing effective treatments to alleviate such painful conditions as temporomandibular joint dysfunction pain and bruxism--tooth grinding. Behavioral scientists have also contributed practical methods of allaying dental fears and anxieties.

Work in craniofacial development is investigating normal developmental patterns and their genetic controls. Useful genetic strains and mutant animal models have been developed to elucidate the complex gene-environmental interactions that can lead to craniofacial malformations such as cleft lip and cleft palate. Salivary gland research is a burgeoning area that continues to yield new discoveries concerning factors in saliva that promote defense against infection as well as aiding in tissue repair. Increasingly, pharmacologists and clinicians are turning to saliva rather than blood samples to monitor and titrate prescription drugs or measure levels of endogenously produced substances. Mineralized tissue research scientists have probed the extracellular ground substances of tissues, finding organic molecules vital in the growth, maintenance and repair of tissues. Some of these substances have been purified and are being used to promote more rapid and superior wound healing or to fill bony defects. Mineralized tissue scientists have also developed a bovine model for the seriously debilitating genetic bone disease, osteogenesis imperfecta.

I would like to leave you with the thought that this sampling of oral health research demonstrates the integration of oral and general biomedical research. The tissues of the mouth are intrinsically interesting and present research challenges. As we progress in basic understanding and in the conquest of oral health problems, we inevitably contribute to the fight against the major killers and cripplers, leading to an improvement in the overall health and well-being of people everywhere.

The budget request for 1985 is $91,096,000, an increase of $2,935,000 over the comparable FY 1984 level.

Mr. Chairman, I would be happy to answer your questions.

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## BIOGRAPHY OF DR. HARALD LÖE

BIRTHPLACE AND DATE: July 19, 1926; Steinkjer, Norway

CITIZENSHIP: United States

SOCIAL SECURITY NUMBER: 383-56-2361

HOME ADDRESS:
2 North Drive
Bethesda, Maryland 20814 U.S.A.

Wife: Inga Children: 2 Adult Children

OFFICE ADDRESS:
National Institute of Dental Research
National Institutes of Health
Building 31, Room 2C-39
Bethesda, Maryland 20205 U.S.A.
Telephone Number: 301 496-3571

DEGREES:

| | |
|---|---|
| 1952 | D.D.S., Oslo University, Norway |
| 1961 | Dr. Odont., Oslo University, Norway |
| 1973 | Honorary Doctorate, University of Gothenburg, Sweden |
| 1980 | Honorary Doctorate, Royal Dental College, Aarhus, Denmark |
| 1980 | Honorary Doctorate, University of Athens, Greece |
| 1980 | Honorary Doctorate, Catholic University of Leuven, Belgium |
| 1983 | Honorary Doctorate, University of Lund, Malmö, Sweden |
| 1983 | Honorary Doctorate, Georgetown University School of Dentistry, Washington, D.C.; U.S.A. |

PRESENT POSITION:

Director, National Institute of Dental Research (NIDR), National Institutes of Health (NIH)

PAST POSITIONS:

| | |
|---|---|
| 1974-1982 | Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington, Connecticut |
| 1972-1974 | Professor of Dentistry and Director of the Dental Research Institute, University of Michigan, Ann Arbor, Michigan |
| 1971-1972 | Associate Dean and Dean-elect, Royal Dental College, Aarhus, Denmark |
| 1962-1972 | Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus, Denmark |
| 1966-1967 | Visiting Professor of Periodontics, Hebrew University, Jerusalem, Israel |
| 1960-1962 | Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Norway |
| 1959-1962 | University Research Fellow, Oslo University, Norway |
| 1957-1958 | Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago, Illinois |
| 1956-1962 | Research Associate, Norwegian Institute for Dental Research, Oslo, Norway |
| 1952-1955 | Instructor in Operative Dentistry, School of Dentistry, Oslo University, Norway |

PROFESSIONAL ACTIVITIES:

Governmental

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|---|---|
| 1984 | Member, NIH Performance Review Board (BID Deputy Directors and Associate Directors and Bureau Division Directors) |
| 1983- | Member, Bureau/Institute/Division Directors Meetings |
| 1983-1983 | Member, Coordinating Committee for Manpower, NIH |
| 1983-1987 | Member, Expert Advisory Committee on Oral Health, World Health Organization (WHO) |
| 1980-1982 | Member, Coordinating Committee on Long-Range Research Plan, NIDR, NIH |
| 1979-1981 | Member, Oral Research Advisory Group, WHO |
| 1975-1976 | Member, Scientific Panel to Evaluate the NIDR Periodontal Disease Research Activity, NIH |
| 1974-1977 | Member and Chairman, Dental Drug Products Advisory Committee, U.S. Food and Drug Administration (FDA) |
| 1974-1978 | Member, Dental Caries Program Advisory Committee, NIDR, NIH |
| 1971-1972 | Member, National Council of Medical Research, Denmark |
| 1969 | Consultant to the Director, NIDR, NIH |
| 1969-1972 | Member, Committee on Dentistry, Danish Foreign Ministry Technical Aid to Developing Countries |
| 1968 | Rapporteur, WHO Conference on Undergraduate Dental Education in Europe |

Corporate

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| 1980-1981 | Member, Professional Advisory Panel on Preventive Dentistry, Johnson & Johnson, New Brunswick, New Jersey |
| 1969-1976 | Consultant, Procter & Gamble Company, Cincinnati, Ohio |

Editorial

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|---|---|
| 1983- | Member, Advisory Board, Journal of Clinical Periodontology |
| 1983-1984 | Member, Journal Committee, American Academy of Periodontology |
| 1979- | Member, Editorial Board, Clinical Preventive Dentistry |
| 1979-1982 | Consultant, Journal of the American Dental Association |
| 1974-1982 | Foreign Expert Member, Journal of the Indian Dental Association |
| 1973-1977 | Member, Editorial Board, Acta Odontologica Scandinavica |
| 1973-1975 | Member, Editorial Board, Journal of Community Dentistry and Oral Epidemiology, Munksgaard, Copenhagen, Denmark |
| 1973- | Member, Editorial Board, Journal of Preventive Dentistry, Masson Publishing USA, Inc., New York |
| 1966- | Founding Editor, Journal of Periodontal Research, Munksgaard, Copenhagen, Denmark |
| 1965-1972 | Board of Directors, Acta Odontologica Scandinavica, Munksgaard, Copenhagen, Denmark |
| 1962 | Associate Editor, Scandinavian Journal of Dental Research, Munksgaard, Copenhagen, Denmark |

Organizational

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|---|---|
| 1983- | Member, Commission on Oral Health Research and Epidemiology, Federation Dentaire Internationale (FDI) |
| 1983- | Consultant, Council on International Relations, American Dental Association (ADA) |
| 1982-1984 | Member, Organizing Committee, The Sixth International Conference on Periodontal Research, Kibbutz Shefayim, Israel |
| 1982-1985 | Electorate Nominating Committee, American Association for the Advancement of Science (AAAS), Section on Dentistry (R) |
| 1980-1981 | Consultant, Periodontal Disease Clinical Research Center, State University of New York, Buffalo, New York |
| 1981-1984 | Member and Chairman, Honorary Membership Committee, IADR |
| 1981-1982 | Member, IADR Nominating Committee |
| 1980-1981 | Member, Organizing Committee, The Fifth International Conference on Periodontal Research, Seattle, Washington |
| 1979-1981 | Member, Annual Meeting Organizing Committee, IADR |
| 1979-1981 | President, IADR |
| 1979- | Member, International Relations Committee, IADR |
| 1979-1982 | Member, Honorary Membership Committee, American Academy of Periodontology (AAP) |
| 1978-1982 | Member and Chairman (1981-1982), Foreign Relations Committee, AAP |
| 1978-1980 | Member and Chairman, General Program Committee, IADR |
| 1978-1980 | Member, Finance Committee, IADR |
| 1978-1982 | Member, National Affairs Committee, AADR |
| 1977-1982 | Member, Board of Directors, IADR |
| 1977-1979 | Vice President and President-elect, IADR |
| 1977-1982 | Consultant, Council on Dental Therapeutics, ADA |
| 1976-1979 | Member, Nominating Committee, AADR |
| 1976-1978 | Member, Organizing Committee, World Workshop in Periodontics, Chicago, Illinois |
| 1976-1978 | Member, Organizing Committee for International Conference on Periodontal Research, Gothenburg, Sweden |
| 1976 | Member, IADR Periodontal Research Program Committee |
| 1976 | Member, Committee for Orban Prize Competition, AAP |
| 1976 | Member, IADR Dental School Research Grant Committee |
| 1976 | Secretary, Jury for the International Preventive Dentistry Award, FDI |
| 1976 | Member, Committee on Outreach Activities, University of Connecticut, Farmington, Connecticut |
| 1974-1979 | Member, Committee on Research in Periodontology, AAP |
| 1974-1975 | Member, Research Policies Committee, University of Michigan Senate, Ann Arbor, Michigan |
| 1974-1975 | Member, Committee on Long-Range Planning, AAP |
| 1973-1975 | Member, Review Panel, Grants and Allocations Advisory Committee, American Fund for Dental Education |
| 1972 | Chairman, International Conference on Periodontal Research, Aarhus, Denmark |
| 1972 | Founding Member of the Scandinavian Society of Periodontology |
| 1970-1971 | President of the IADR Periodontal Research Group |
| 1969-1974 | Chairman and Member, IADR Basic Research in Periodontal Disease Award Committee |
| 1969 | Co-Chairman, International Conference on Periodontal Research, Rochester, New York |
| 1969 | Co-Chairman, Scandinavian Symposium in Prosthetics and Periodontology, Aarhus, Denmark |
| 1968-1970 | Member, Board of Trustees, Danish Dental Association |
| 1967-1971 | Consultant, Committee on Foreign Relations, AAP |
| 1966 | Secretary, Pathology Section at the World Workshop in Periodontics, Ann Arbor, Michigan |
| 1965 | Chairman, Scandinavian Symposium in Periodontology, Aarhus, Denmark |
| 1964 | Founding Member, Western Danish Society of Periodontology |
| 1959-1961 | Chairman and Member of the Committee on Postgraduate Education, Oslo Dental Society, Norway |
| 1953-1957 | Member, various administrative committees, Norwegian Dental Association |

Other

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|---|---|
| 1959-1962 | Private practice in periodontics |
| 1952-1957 | Private general practice |

HONORS

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|---|---|
| 1983 | International Award of the Friends of the University of Connecticut School of Dental Medicine |
| 1983 | Lister Hill Memorial Lecture, University of Alabama, Birmingham |
| 1983 | Daniel F. Lynch Award, Dental Society of Greater Waterbury, Connecticut |
| 1983 | International Lecturer of the Year Award, Academy of International Dental Studies |
| 1982 | Gold Medal, University of Ghent, Belgium |
| 1982 | Citation, University of California School of Dentistry Centennial Commencement, San Francisco |
| 1982 | Award of Merit, Hartford Dental Society, Connecticut |
| 1979 | Irving Glickman Memorial Lecture, Tufts University, Boston, Massachusetts |
| 1978 | William J. Gies Periodontology Award |
| 1977 | Arthur Merritt Memorial Lecturer, Baylor University, Dallas, Texas |
| 1976 | Certificate of Achievement, Connecticut Society of Periodontists |
| 1973 | Massachusetts Dental Society International Award |
| 1972 | Honored by Her Majesty the Queen of Denmark (Knight of Danebrog) |
| 1972 | American Society of Preventive Dentistry International Award |
| 1969 | International Association for Dental Research Award for Basic Research in Periodontics |
| 1969 | Aalborg Dental Society Prize of Honour, Denmark |
| 1965 | Erik Berg Foundation Prize of Honor, Copenhagen, Denmark |
| 1959 | Ingv. Stokke Prize for Outstanding Dental Research, Oslo, Norway |
| 1959 | Norwegian Dental Association 75th Anniversary Prize |
| 1982 | Honorary Member, Belgian Periodontal Society |
| 1982 | Honorary Member, Societe Francaise de Parodontologie |
| 1982 | Corresponding Member, Swiss Periodontal Society |
| 1981 | Honorary Member, Scandinavian Society of Periodontology |
| 1981 | Fellow, American Association for the Advancement of Science (AAAS) |
| 1980 | Fellow, American College of Dentists |
| 1978 | Fellow, International College of Dentists |
| 1978 | Honorary Member, Centro de Estudios de Recursos Odontologicos para el Nino |
| 1976 | Honorary Member, Horace Wells Club, Hartford, Connecticut |
| 1974 | Corresponding Member, Finnish Dental Society |
| 1972 | Honorary Member, South African Society of Periodontology |
| 1970 | Honorary Member, Cercle de Parodontie, France |
| 1969 | Honorary Member, Western Society of Periodontology, Denmark |
| 1968 | Honorary Member, Colombia Society of Periodontology, Colombia, South America |
| 1966 | Corresponding Member, Swedish Dental Association |
| 1965 | Honorary Member, Milwaukee Dental Forum, U.S.A. |

MEMBERSHIPS:

American College of Dentists (ACD)
American Dental Association (ADA)
American Academy of Periodontology (AAP)
American Association for Dental Research (AADR)
International Association for Dental Research (IADR)
International Association for Dental Research Periodontal Research Group
American Association for Dental Research Periodontal Research Chapter
International College of Dentists (ICD)
Danish Dental Association (DTF)
Norwegian Dental Association (NTF)
Scandinavian Association for Dental Research (NOF)
Sigma Xi, The Scientific Research Society

PUBLICATIONS:

Author of more than 200 publications.

### BUDGET IMPACT

Senator WEICKER. Again, let me ask you a question as to where you will be impacted the most by the administration's budget?

Dr. LÖE. Our budget shows a slight reduction in the number of grants that we will be able to fund. We have a small reduction in the number of trainees. And I would also think that we probably would have a reduction in a number of the contract areas that will prevent or postpone some of the clinical trials that we have in mind.

Senator WEICKER. Are these all matters that you can live with, or is there anything of particular concern to you?

Dr. LÖE. The changes from the current year are reasonably small and, I believe we can live with them.

### REORGANIZATION IN NIDR

Senator WEICKER. I understand that you're taking the Dental Institute through some organizational changes. There apparently will be a consolidation of grants and review components and you're moving to change the character and the funding of future dental research institutes and centers.

Would you give us a brief description of what you have in mind and how you believe it will improve the work of the institutes?

Dr. LÖE. These are two separate areas. One deals with NIDR reorganization as it relates to the Extramural Program area. We have collapsed six management areas into three, the purpose of which was to streamline the organization and to transfer some of the money that had been used in administrative costs to the support of actual research.

This realignment has proceeded in an orderly manner through 1983 and partly into 1984. We have expanded the former National Caries Program to include all oral diseases, and it is now called the Epidemiology and Oral Disease Prevention Program.

The Intramural Program has been less involved in these realignments. Some of the researchers from the National Caries Program working in microbiology and immunology have been transferred to the Intramural Program. By and large these changes have been completed, and I am delighted to report that increases in the effectiveness of the programs and reductions in overhead have come about.

### RESEARCH CENTERS

Senator WEICKER. What will happen to the dental research institutes? I notice they are currently funded in Alabama, North Carolina, Pennsylvania, Michigan, and Washington State.

Dr. LÖE. These institutes and centers were established in the 1960's for the purpose of broadening the science base for dentistry and to attract more basic scientists into dental research. These five institutes, as you mention—Michigan, Pennsylvania, Washington, North Carolina, and Alabama—have been very successful both in broadening the base for dental science and in attracting basic scientists to dental research.

However, the 1980's are different from the 1960's. There are now many more dental schools that are able to take on quality research activities. I should also mention that these five institutes have been supported for almost 20 years. The competition for these centers was closed in the early 1970's. One of the major purposes of changing the program is to open up the competition to other dental schools. We will change somewhat the character of these centers; they will be more interdisciplinary, and better able to bridge the gap between basic research and clinical application. The new centers will be smaller, both in terms of critical mass of people and funding. By the end of this decade we hope to have somewhere between 15 and 20 of these centers in various parts of the country.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. I have further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the Fiscal 1985 NIH Budget -- Small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc.

To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: During the budget formulation process NIDR has considerable input. The first stage in the formulation process is to develop a commitment base that will support adequately all ongoing research and provide sufficient funds for administrative management.

A preliminary budget is submitted to NIH from NIDR which contains sufficient funds for currently ongoing research, but includes funds for research that NIDR would like to give increased emphasis.

At each level of the review process -- NIH, PHS, DHHS, OMB -- the preliminary budget estimate is adjusted in accordance with priorities and policies at that level. These revisions are based on the broader scope at which each level functions, as the budget approaches completion. At each point in the review process, the NIH as a whole can appeal any decision made at a higher level. While the final total dollars are determined by OMB, there is a substantial amount of negotiation before that figure is arrived at.

### BUDGET IMPACT

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: Under the budget request the NIDR will fund seven fewer competing research project grants, 11 more noncompeting research project grants, and thirteen fewer training positions than are planned for funding in FY 1984. Contract funding will remain level and funding for centers will decrease slightly. Through a reallocation of resources, NIDR will fund two additional specialized centers while reducing, based on programmatic considerations, support for the existing non-categorical dental research institutes and centers.

### GRANTS

Question: To what extent will your new and continuation grants be funded below full cost levels - and what important research will be delayed or eliminated as a result?

Answer: The NIDR anticipates negotiating direct costs of new grants downward by approximately 7 percent and continuation grants by approximately 8 percent. Specific research activities will not be postponed, but the rate of progress will be slowed.

## RESEARCH CENTERS

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84? What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: Although total funding for centers will remain approximately level, the NIDR does not propose to maintain the same centers program in FY 1985 that we had in FY 1984. In FY 1985 support for the current non-categorical dental research institutes and centers will be reduced, so that funds will be made available for developing a new program of centers with greater focus. This decision was based on programmatic considerations rather than budget constraits.

This decision represents the first step in our attempt to develop a centers program responsive to the needs of the future. Although the current centers have been highly successful in their two main objectives of attracting basic scientists into dental research and upgrading the national dental research capability, it was concluded by staff and advisors that these non-categorical centers are no longer as appropriate as they once were. Today, a sufficiently strong knowledge base exists to enable us to plan combined basic and clinical programs that will facilitate the application of basic knowledge to the prevention and treatment of oral health problems. With the impressive base of knowledge that has been developed, it is now clear that the needs of the future demand more interdisciplinary efforts. To develop the best possible research teams, the NIDR will therefore seek competitive applications from highly qualified institutions with strong potential for center development. These efforts to establish new categorical and thematic centers should lead to greater research opportunities.

## TRAINING

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: Although there is a small increase in the FY 1985 NIDR training budget, the NIDR will be able to support 13 fewer fulltime training positions.

The impact of this decrease in the number of dentists preparing for research careers is potentially significant. The recently completed NIDR Long-Range Research Plan reviews the remarkable dental research accomplishments and calls attention to the need to move quickly to incorporate basic findings into clinical trials and practice. The plan addresses the pressing need for dentist-investigators able to carry this research forward as well as to communicate clinical problems to the basic scientist.

The problem of the general shortage of clinical researchers has been cited by the National Academy of Sciences in its 1983 report on research personnel needs. Each of the major dental professional organizations as well as the NIDR advisory committees and the

National Advisory Dental Research Council have called attention to the specific and serious problems concerning the future availability of dental research manpower.

Prompted by these expressed concerns and statistics, the NIDR initiated a special reassessment of its research training support programs this past year. It was concluded that the existing NRSA research training support programs are meeting the needs of Ph.D. level biological scientists preparing for dental research careers but not the needs of dentists. With the assistance of external expert consultants, a new research manpower development program similar to the recently announced NIH Physician-Scientist Program but which addresses the unique needs of dental medicine has been formulated. This proposed Dentist-Scientist Program was presented to the NIDR National Advisory Dental Research Council at its January 1984 meeting.

## ADDITIONAL FUNDING

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: To maintain the same level of effort in fiscal 1985 as in fiscal 1984, $6,026,000 in additional funding would be required.

## FTEs

Question: The Budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect of research?

Answer: The NIDR's share of the proposed reductions in NIH staff levels is 15 FTEs. These reductions will be made in intramural research and research management and support. Because the staff reductions will be accomplished through attrition, we cannot anticipate the extent of the impact on either intramural research or research management and support. However, every effort will be made to minimize the impact on scientific research.

## REORGANIZATION OF INSTITUTE

Question: Dr. Löe, we understand you are taking the Dental Institute through some organizational changes. There apparently will be a consolidation of grants review components. And you are moving to change the character and method of funding of future dental research institutes and centers.

Please give us a brief description of what you have in mind and how you believe it will improve the work of the Institute.

Answer: There will be a consolidation of the components that make up the Extramural Program where the grants programs are administered but no reduction in the support of the various program components is planned. The three new Branches will combine Dental Caries and Restorative Materials Research; Periodontal and Soft Tissue Diseases; and Craniofacial Anomalies, Pain and Behavior. We expect the result of this streamlining will be that a greater breadth of scientific administrative talent can be brought to bear on any given subject field, while, at the same time, overhead will be substantially reduced.

This new program will be charged with studying not only caries but also the periodontal diseases and other oral diseases and disorders. We are also establishing a new program in epidemiology and oral disease prevention that will utilize the expertise of the former National Caries Program. Finally, we plan an expansion of health promotion and technology transfer activities to encompass the full range of oral diseases and conditions.

## RESEARCH CENTERS

Question: Your plan apparently is to fund centers focused on a specific disease, such as caries, rather than put your money into overall basic research. How would you handle basic research in the future -- through regular grants?

Answer: Regular research grants and the intramural research program will continue to provide the major foundation for the NIDR basic research activities. These basic science activities constitute over 70% of the NIDR budget. It should also be emphasized that basic research will be included in the categorical and thematic centers.

Question: What will happen to the dental research institutes and centers currently funded -- those in Alabama, North Carolina, Pennsylvania, Michigan and Washington State?

Answer: Direct NIDR support for the non-categorical research institutes and centers at Alabama, North Carolina, Pennsylvania, Michigan and Washington will be gradually reduced over the next 4-year period. These centers will be funded at a level of 65% in FY 1985, 40% in FY 1986 and 20% in FY 1987. After that period, direct support as non-categorical centers will cease. It is anticipated that throughout this transition period, the center investigators will obtain support through regular grants, program projects or the new categorical centers.

Question: How many of the so-called thematic centers do you plan to fund and how much money do you plan to spend on them? How does this compare with what you are doing now?

Answer: The recently completed NIDR Long Range Plan recommends the development of approximately 18 new categorical or thematic centers by 1989 at a total cost of approximately $16 million dollars. In the current year (FY 1984), we will be funding 10 centers (5 non-categorical and 5 categorical) at a cost of approximately $10 million dollars.

## VACCINE

Question: For many years, your Institute has been working on a vaccine to prevent dental caries (tooth decay).

Is the development of such a vaccine anywhere in sight?

Answer: Progress toward a caries vaccine continues to be slow but steady. Both animal and short-term human experiments have shown that antibacterial activity can be induced in saliva by vaccination with whole cells of cariogenic streptococci. Current efforts are focused on attempts to identify the most potent antigenic cell fraction or cell product. Experiments are also in progress to determine whether certain adjuvants can potentiate the effectiveness of these antigens.

Question: Are you contemplating human clinical trials any time soon?

Answer: We have begun discussions with the FDA regarding their requirements for such a study.

## DENTAL SEALANTS

Question: With the advent of dental sealants, is there any inclination to reduce the effort to develop a vaccine for caries?

Answer: Although sealants, if more widely used, as well as fluorides are capable of bringing about further reductions in caries, we continue to give high priority to the development of other potential preventive methods which promise to have improved cost-effectiveness characteristics and could be easily delivered to the public. A caries vaccine would fit into this category.

Question: Where do you stand in the work to develop dental sealants and how soon will they become standard in dental practice?

Answer: Dental sealants are already well developed. The National Institute of Dental Research and the Office of Medical Applications of Research, NIH, jointly sponsored a consensus development conference on pit and fissure sealants in the prevention of dental caries in December, 1983. The purpose of the conference was to evaluate the effectiveness, safety and feasibility of the use of sealants. After hearing a day and a half of presentations by experts on dental sealants, a Consensus Panel of biomedical investigators, practicing dentists, academicians, a dental hygienist, a statistician, and representatives of public interest groups considered the evidence and concluded that "the placement of sealants is a highly effective means of preventing pit and fissure caries. It is safe. It is currently underused in both private and public dental health care delivery systems...Because dental caries is still a disease common to most young people in the United States and in other countries of the world, such reductions would substantially improve the health of the public and reduce the expenditures for treatment of dental disease...." The Panel urged practitioners, dental health agency directors, and dental educators to incorporate the appropriate use of sealants into their practices, programs and curricula. The proceedings of the conference have been published as a special supplement to the February 1984 issue of the Journal of Dental Education. The Consensus Development Conference has generated a new interest in dental sealants among the dental profession and the general public. We are optimistic that the use of pit and fissure sealants will increase dramatically as a result of this conference.

Question: Are sealants safe, particularly for children?

Answer: Yes. The Consensus Conference thoroughly evaluated the research data on the safety of sealants, and concluded that there are no safety questions concerning their use. Sealants are especially intended for use in children to protect the occlusal surfaces of teeth during the period of maximum susceptibility to caries.

## LONG-RANGE RESEARCH PLAN

Question: Can you briefly describe for us your Long-Range Research Plan which you have entitled "Challenges for the '80's"?

Answer: The National Institute of Dental Research (NIDR) has just completed a long-range research plan (FY 1985-1989) entitled Challenges for the Eighties. The document was prepared under the guidance of a Long-Range Plan Coordinating Committee whose members represented the research community, NIDR advisory bodies and NIDR staff. Over 200 scientists participated in the project. The Plan describes the magnitude of the health problems and condition, summarizes the state-of-the-science and highlights key accomplishments. In addition, research objectives and strategies to achieve those objectives are specified for each area. The Plan provides a blueprint for the future with the hope of facilitating research and of communicating findings within the dental community and the public at large.

## ROOT CARIES

Question: Although a significant reduction in the incidence of caries has been achieved, we understand that "root caries" is an increasing problem among older people.

What can you tell us about "root caries" and what you are doing to deal with it?

Answer: Root caries can occur when the surface of the root becomes exposed to the oral environment because of recession of the tissue around the neck of the tooth. The disease is found mostly in older persons, especially those who have suffered tissue recession because of periodontal diseases. As a part of a nationwide epidemiologic study of the oral health of adults, which we will begin this year, we will collect detailed data on the prevalence of root caries. From several small surveys there is evidence that root caries may be a growing public health problem, especially as more teeth are retained into adult life. The cause and prevention of this disease are not yet established. We are developing research programs on the etiology of root caries using research grant support, and have in progress a clinical trial to test the effectiveness of fluoride in preventing root caries.

Question: How much is the Institute spending on the problem in fiscal 1984 and how much will it invest in the coming fiscal year?

Answer: During the current year, approximately $300,000 is being spent on research on root caries. In FY 1985, we expect to spend about $1.75 million on such research.

This includes that part of our planned national survey of the oral health of adults which focuses on establishing age and geographic-specific prevalence of root caries. Interest in this disease is rapidly increasing, and we expect our support of research in this area to continue to increase.

## PAIN RESEARCH

Question: We understand you are doing some experimental and clinical work on oral pain. What advances are you making and what are some of the more far-reaching applications of the Institute's pain research?

Answer: Recent advances have been made in our understanding of how pain messages are transmitted from the oral-facial region and how these messages can be modified by control systems in the brain itself.

Naturally occurring morphine-like drugs such as the enkephalins appear to play an important role in our ability to suppress incoming pain messages. They interact with other chemical mediators in the brain such as serotonin. Recent studies have determined that chemical mediators or neurotransmitters such as enkephalin and serotonin have direct inhibitory actions on nerve cells that receive pain messages from the oral-facial region. These findings provide the morphological basis for the pain-suppressing action of these neurochemicals.

A promising discovery is that there are many different kinds of chemical transmitters and receptors that can turn off pain. With some more work in this area, we may be able to develop completely new classes of pain relievers that overcome the problems of side-effects and tolerance to the narcotic drug family, and add quality to the lives of patients with chronic pain.

Recent studies show that humans and other primates can discriminate very fine differences in intensity between painful stimuli applied to the oral-facial region. The classes of nerve cells in the brain responsible for these fine discriminations have been identified. Morphine-like drugs suppress the activation of these nerve cells and also decrease the ability of primates to make fine discriminations in the pain range. These discoveries have substantially increased our knowledge about specialized pathways in the brain encoding pain sensations.

Significant advances also have been made in improving pain assessment methods in humans. Our ability to provide more objective and quantitative measures of the human pain response has increased. Both verbal and non-verbal techniques are being improved. Non-verbal methodologies have utilized facial expressions, evoked potential responses to externally administered pain stimuli, and analyses of electroencephalograms to evaluate the response to pain stimuli. Knowledge derived from these multiple approaches will be helpful to the clinician in both the diagnosis of pain problems as well as the assessment of treatment effectiveness.

The Pain Research Facility at the NIH was opened in March, 1983 under NIDR's leadership. Within one year the patient load has increased from 35 per week to over 100 per week. Five other Institutes (NCI, NIMH, NINCDS, NHLBI, NICHD) and the Clinical Center are collaborating with NIDR scientists on studies of acute and chronic pain with an emphasis on improved methods of pain assessment and the development of new pain control agents. Recent research advances include the following: (a) Well-controlled clinical trials have revealed that tricyclic anti-depressant drugs such as amitryptyline are effective in the treatment of painful diabetic neuropathy and postherpetic neuralgia. These drugs appear to influence pain separate from their effect on depression. (b) New studies are underway to evaluate muscle-relaxant drugs and anti-inflammatory agents in the treatment of craniomandibular myofascial pain. (c) Endogenous opiate-like chemicals are released during oral surgical procedures and appear to be associated with lower levels of postsurgical pain.

These findings suggest that naturally occurring opiate-like, pain-suppressing chemicals are released during stressful procedures and modify pain.

These experimental and clinical research advances should lead to major improvements in methods of controlling pain. Increased knowledge about chemical mediators involved in pain transmission and its suppression will lead to the development of new pharmacological agents useful in pain control. The further understanding of natural conditions under which the brain's own pain-suppressing systems can be activated will provide patients with insights into controlling their own pain.

### LONG-RANGE PLAN

Question: We noted in your presentation that you have prepared a report "Challenges for the Eighties." Would you please provide the Committee with copies of the report?

Answer: We have provided the Committee with copies of the report.

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## Questions Submitted by Senator William Proxmire

### DISORDERS OF STRUCTURE, FUNCTION AND BEHAVIOR

Question: Dr. Löe, your 1984 budget submission indicated that the Institute planned to spend $26,142,000 on disorders of structure, function and behavior. Despite the fact that the Congress added $7.5 million to your budget as submitted, your current plan is to spend $17,135,000 on disorders of structure, function and behavior. What caused this dramatic reduction in your initial estimate?

Answer: During the realignment of the Institute, programs were consolidated and funds were shifted from the program activity, Disorders of Structure, Function, and Behavior to the program activity, Diseases of the Teeth and Supporting Tissues. This represents a more effective alignment of functions and personnel within the Institute. By no means will research be inhibited under the program activity Disorders of Structure, Function and Behavior.

### TRAVEL

Question: Last year you estimated expenditures of $278,000 on travel in fiscal year 1984. Your current projection for 1984 travel is $340,000, an increase of more than 20 percent. Why was your initial travel estimate so wide of the mark?

Answer: The NIDR requires the additional funds in FY 1984 to conduct on-site reviews of its new categorical and thematic centers which requires large teams of site visitors. In addition there is increased research grant and contract monitoring and review efforts. The NIDR has also increased its collaboration with the extramural community and expanded its information transfer activities.

### OTHER SERVICES

Question: Your 1984 budget for the subcategory "Other" under "Other Services" was originally $2,191,000. That has now been cut to $1,332,000 despite a Congressional add-on to your overall 1984 budget. What sorts of activities are covered by the subcategory "Other" and why did you cut your original estimate for 1984?

Answer: Laboratory services and support needs are covered by the "Other" subcategory. As part of program realignment, a new Epidemiology and Oral Disease Prevention Program was established in the place of the former National Caries Program. As part of this plan, two new caries centers will be funded. The realignment allowed a transfer of "Other Services" funds to the Extramural Program to help support these caries centers.

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## Letter From Dr. Harald Löe

MAY 30 1984

The Honorable William Proxmire
United States Senate
Washington, D.C. 20510

Dear Senator Proxmire:

This is in response to your letter of May 4 requesting that we respond to a series of questions concerning the decision of the National Institute of Dental Research (NIDR) to change the emphasis of the research activities funded by the centers mechanism.

Enclosed is the list of your questions and the NIDR response. I would like to emphasize the fact that the decision to implement the proposed changes in the NIDR center activities was not based on the August 16 meeting alone. The decision was based upon advice and recommendations of several program evaluation panels, the NIDR Special Grants Review Committee, the National Advisory Dental Research Council as well as the recommendations emanating from the August meeting. These decisions have been discussed widely with groups such as the Council of Deans of the American Association of Dental Schools and the membership of the American Association for Dental Research who have generally concurred with the plan.

I hope this information will be of assistance to you.

Sincerely yours,

Harald Löe

Harald Löe, D.D.S., Dr. Odont.
Director
National Institute of Dental Research

1. Why did the review panel of August 16 contain few, if any, active scientists?

Response:

The group of advisors convened by the National Institute of Dental Research (NIDR) on August 16, 1983, was constituted in such a manner so as to provide a broad overview of the present and future needs of dental research. In addition, individuals were selected who had a close knowledge of the Dental Research Institutes and Centers (DRICs) program such as representatives of the original planning committee which developed the concept of the Centers prior to their initiation and individuals who participated in oversight of the Centers over the years through membership on the National Advisory Dental Research Council and the Dental Research Institutes and Special Programs Advisory Committee. The advice sought was of a broad programmatic nature rather than a review of specific projects. For this reason senior members of the academic and research communities were considered the most appropriate source of the advice sought.

2. Why were members of the DRICs not invited to the August meeting?

Response:

Since the NIDR was seeking an overview of the role of Centers in the context of present and future programmatic activities, we did not believe that representation of the special interests of specific grantees would be appropriate to the broader issues to be discussed. The views of the Center leaders were already known to the staff and to the advisors. We believe that the data provided by staff, together with the personal knowledge and experience of the participants, constituted sufficient objective information for the advisory group to consider in developing its recommendations.

3. Why weren't program leaders of the NIDR present at the August meeting?

Response:

The views of the program leaders were sought prior to and following the August meeting.

4. What is the basis for your judgment that specialized centers are more cost effective?

Response:

The decision to change the focus of Center activities supported by NIDR was based upon program need. Over the years, the five noncategorical DRICs have been highly successful in broadening and strengthening the scientific base underlying oral health research. Contributions from the Centers and from other research institutions have set the stage for more focused research efforts which could promise practical health benefits to the Nation. Accordingly, several advisory groups have recommended that NIDR initiate categorical or thematic centers focused on specific oral health problem areas. A change in the emphasis of Center activities is expected to achieve a more appropriate balance between basic and applied research supported by the Institute. Without such balance, the activities of the NIDR would be less cost effective.

5. Are the DRICs your weakest investment in oral health research? If so, how did you arrive at that decision? If not, shouldn't the weakest funding areas be eliminated?

Response:

The quality of research in the DRICs has never been in dispute. Since these Centers were first established, their progress has been continually evaluated through periodic peer review, staff monitoring, and oversight review by the National Advisory Dental Research Council. The NIDR Centers were also included among the NIH Centers evaluated by the Rand Corporation in 1977. These evaluations have clearly indicated that the Dental Research Institutes and Centers have been highly successful in accomplishing their main objectives. The question addressed by the decision to change the focus of the Center activities is that of the critical needs and opportunity of oral health research today and for the foreseeable future. As previously stated, several advisory groups have reccommended that NIDR initiate categorical or thematic centers focused on specific oral health problem areas. The major intent of the decision is to achieve appropriate program balance.

6. How do you judge the relative value of your research investment mechanisms? Are grants better than program projects? Are centers better than grants? Worse than grants? How do you know?

Response:

All research mechanisms utilized by the NIDR are valuable in accomplishing the Institute's overall mission. It is also important to achieve program balance through the use of appropriate mechanisms. Initiation of program projects and specialized centers will serve to form the necessary link between basic and applied research so that the fruits of oral health science may be more readily applied to solving oral health problems.

7. If the specialized center concept is worthy, can't they compete for program projects?

Response:

It is conceivable that activities similar to specialized centers could compete for program project grants. However, the Center mechanism provides more stable, long-term support and thus serves as a better mechanism for developing activities which combine basic and clinical approaches to all health problems.

## NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

### STATEMENT OF DR. LESTER B. SALANS, DIRECTOR

**ACCOMPANIED BY:**

**DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**L. EARL LAURENCE, EXECUTIVE OFFICER, NIADDK**

**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### BUDGET REQUEST

Senator WEICKER. Next we shall hear from the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The Institute has responsibility for five debilitating diseases whose estimated economic costs, we're told exceed $100 billion.

The budget request for the Arthritis and Diabetes Institute is $475 million or about $13 million more than the fiscal 1984 appropriation.

The lead witness for the Institute is Dr. Lester Salans. We welcome you back, Dr. Salans. And why don't you go ahead.

Dr. SALANS. Thank you very much, Senator Weicker.

I am pleased to be here before the committee to represent the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases [NIADDK]. Let me introduce my colleague on the left, Mr. Earl Laurence, Executive Officer of the NIADDK.

Mr. Chairman, you know full well that the NIADDK is responsible for some of this country's most chronic debilitating diseases which, as you indicated, cost the economy an enormous amount each year. The diseases for which our Institute are responsible probably touch every American household. And while each of these diseases are in themselves very important, it's only when you consider the combined effects of arthritis, diabetes, digestive and kidney diseases, diseases of the skin, of the bone, of the blood system, endocrine diseases, and disorders related to nutrition, metabolism and the urinary tract as well as areas of basic science for which we are responsible, that the full impact, and magnitude of our area of responsibility can be appreciated. In my opinion this is too often overlooked.

I am pleased to report to you today that as a result of research that is supported by our Extramural Research Program and research being conducted by our intramural scientists, we are making significant progress in each of these areas and generating very exciting opportunities for the future.

I have highlighted some advances and opportunities in my full statement and will be happy to discuss them in more detail in response to any questions you may have.

Let me conclude by saying that these and other advances and opportunities have led to an unprecedented sense of optimism and expectation, not only within the NIADDK, but also in the scientific and public community concerned with this Institute.

The Institute is committed to doing everything possible to maintain the momentum that has been generated to make sure that the potential for the future is realized.

PREPARED STATEMENT

I'd be pleased to answer any questions that you might have, sir.

[The statement follows:]

## STATEMENT OF DR. LESTER B. SALANS

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) is responsible for a national program of research on a wide spectrum of diseases affecting virtually every family in the Nation; including arthritis, bone and skin diseases, diabetes and diseases of endocrinology and metabolism such as cystic fibrosis, digestive diseases and nutritional disorders, and diseases of the kidney, urinary tract and blood. These diseases are among the most common, chronic, disabling and costly facing this country; they affect over 40 percent of our population, exact an enormous toll in terms of human suffering and their collective economic impact exceeds $100 billion annually.

NIADDK's Research Program. To conquer these diseases, the Institute supports and conducts a vigorous multifaceted research program built on a foundation of innovative basic science and extended by clinical investigations. As a result of this program scientists have made impressive, indeed remarkable, gains which are contributing to today's and tomorrow's improved health care.

Although these diseases relate to different body systems and organs, they often possess common pathogenic mechanisms which can be identified and understood through similar studies in molecular biology, immunology, metabolism, endocrinology and genetics. Thus, new knowledge generated in one group of diseases clarifies and contributes to progress in the fight against the others.

Arthritis, Musculoskeletal, and Skin Diseases. Rheumatoid arthritis is one of the major crippling diseases in this country and is consequently one of the Institute's highest research priorities. Some forms of rheumatoid arthritis have an immunologic basis and significant progress has been made in identifying several of the most fundamental immunopathologic factors involved. As a result, new therapies directed at the immune system have been developed and shown to be efficacious. Two years ago, I reported to you that a high percentage of patients with advanced rheumatoid arthritis which had proven resistant to any other method of treatment showed significant clinical improvement after radiation of the body's lymph nodes, a therapy called total lymphoid irradiation. I am pleased to report to you now that the majority of these patients are still in remission.

Equally promising is the progress in research on the inflammatory and destructive processes which characterize the relentlessly progressive deterioration of joints of persons with rheumatoid arthritis. Better understanding of these processes has led to the development and testing of new therapeutic agents such as the non-steroidal antiinflammatory agents, which act against arthritis by blocking the prostaglandins, and to discovering the scientific basis for the efficacy of established therapeutic agents such as gold compounds. The enzyme collagenase has been shown to participate in the breakdown of tissue in rheumatoid arthritis and a new drug, 13-cis retinoic acid, has been discovered to suppress arthritis in an experimental animal model by blocking collagenase production by joint tissue.

Osteoarthritis is the most common form of arthritis in man, affecting more than 16 million Americans. This form of arthritis is characterized by progressive degeneration of joint cartilage and overgrowth of bone, often producing pain and immobility. New insights into the biomechanical forces on and biochemical changes occurring in cartilage and bone provide, for the very first time, a promising framework upon which future disease prevention and effective treatment can be based. In the meantime, recent improvement in biomaterials and design of man-made joints have now made it possible to report an improved postoperative success rate, in total hip and total knee replacements. In a recent three to five year follow-up of 183 such total knee operations, 90 percent of the patients with the latest devices had good to excellent results.

Unique compounds have recently been isolated from human and animal bones which specifically stimulate the growth and regulate the remodeling of new bone. These compounds hold great promise for repairing malformed bones and fractures, and for improved management of osteoporosis.

In research on the hereditary, often fatal, blistering disease(s), epidermolysis bullosa, the new biotechnology of monoclonal antibodies has been used to demonstrate a deficiency of a previously unknown constituent of the skin, the anchoring fibrils; the absence of these fibrils appears to promote blistering in this tragic disease.

Diabetes, Endocrinology and Metabolic Diseases. It has long been known that diabetes mellitus is not a single disease but a group of disorders with many different underlying causes. Researchers are continuing to gain an increased understanding of the causes of some types of diabetes mellitus. For example, some non-insulin dependent diabetics have specific mutations in their insulin genes and as a result produce an abnormal insulin molecule incapable of lowering blood glucose levels. In others, several specific defects in the action of normal insulin to remove and metabolize blood glucose have been discovered. Identification of specific defects in insulin action should enable future researchers to develop specific corrective treatments for these types of diabetes.

There is increasing evidence that in many patients with insulin dependent diabetes (IDDM), destruction of insulin-producing beta cells is the result of an autoimmune process. It now appears that susceptibility to this process is conferred by an as yet unidentified diabetes gene(s) located on chromosome 6. This diabetes gene(s) is closely positioned near other genes which regulate the body's immune system, for example genes which produce HLA antigens. In some populations more than 90 percent of IDDM patients possess one or two specific HLA antigens. Application of the new techniques of molecular biology and immunology should enable researchers to locate and identify the diabetes gene(s), to determine how it causes destruction of beta cells and to develop specific treatments. The use of HLA antigens to detect persons at risk for IDDM may permit therapeutic intervention before an individual's capacity to produce insulin has been destroyed.

Exciting progress is continuing in the area of transplantation of insulin-producing pancreatic islets. Investigators are now able to prolong the survival of islets transplanted from normal rats into a different strain of diabetic rats and to reverse the diabetes without administration of immunosuppressive drugs by transfusing the diabetic recipient animals with donor blood irradiated with ultraviolet light. This promising approach may eventually find application in the treatment of human diabetes, as well as in other types of organ transplantation.

Last year I told you how advances in recombinant DNA techniques have resulted in the development of synthetic human insulin and growth hormone. This year they are a practical reality, commercially produced and clinically as efficacious and risk-free as their natural counterparts. Man-made human growth hormone will soon be available in unlimited amounts to prevent and treat certain types of dwarfism and growth retardation.

Utilizing new molecular biology techniques, investigators have succeeded in permanently incorporating into mice the ability to produce rat and human growth hormones. They microinjected fertilized mouse eggs with growth hormone genes and the resulting offspring grew significantly larger than their normal litter mates. This and similar advances with other genes provides not only an opportunity to learn about gene expression in health and disease, but also a potential means for ultimately correcting hereditary diseases.

Vigorous extramural research efforts continue in the area of cystic fibrosis (CF), the most common lethal hereditary metabolic disease of white children. Abnormal electrolyte transport in different tissues and organs appears to be a basic defect in CF. Past studies have pointed to an apparent impairment in the reabsorption of sodium in sweat, salivary, and pancreatic ducts. The most recent studies demonstrate that the defect is one of reduced ability to reabsorb chloride in sweat ducts, and decreased membrane permeability to chloride ion in general. Identification of this basic defect may lead to more effective treatment of CF patients through better management of electrolyte balances.

Digestive Diseases and Nutrition. Peptic ulcers affect a large percentage of our population and account for considerable morbidity, many lost work days, and high health care costs. Ongoing research has resulted in impressive improvements in peptic ulcer therapies. The most recently studied and introduced antiulcer agent, ranitidine, is even more effective in blocking gastric acid secretion than its related predecessor and has been shown to be free of undesirable feminizing side effects seen in male patients who receive large doses of the former drug. Another new drug, sucralfate, has been demonstrated to bind directly to proteins at the ulcer site to form a protective coating and to reduce the recurrence rate of peptic ulcers.

Diarrhea from infectious causes contributes significantly to infant mortality and adult morbidity even in western societies. Recent research has demonstrated that a number of enteric infections are mediated by attachment of the infecting bacteria to the surface of the intestine with the aid of hair-like appendages, "pili." These structures adhere to specific "binding sites" on the intestinal surface; thus, the attached bacteria can resist being washed out of the digestive tract and continue in their persisting infection. Future therapies will focus on interfering with this newly recognized mechanism underlying the adhesion phenomenon.

Vastly improved surgical techniques and patient selection, and use of a new immunosuppressive drug, cyclosporine, have resulted in significantly improved survival rates in whole liver transplantation in children. The Institute will continue to support research in this area so that the full therapeutic potential of this therapy can be realized.

Studies in the area of obesity have shown that fat in the abdomen is more sensitive to lipolytic (fat-degrading) hormones than fat in other areas of the body. Intraabdominal fat empties its degradation products, fatty acids and glycerol, directly into the portal vein which leads directly to the liver. Since the liver is the primary source of triglycerides ("neutral fat") and glucose in blood, this may explain the increased risk for elevated triglyceride and glucose blood levels in obese individuals whose excess fat is predominantly in the abdomen.

Kidney, Urologic and Hematologic Diseases. The Institute is in the midst of organizing a multicenter cooperative clinical study which seeks to define the influence of dietary protein restriction on the progression of chronic kidney disease and the degree of renal insufficiency. This very important study will test whether dietary protein restriction reduces the rate of downhill progression of chronic kidney disease and--if it is effective--whether this therapy is nutritionally safe.

"Glomerulonephritis" comprises a group of serious kidney diseases which are associated with a variety of abnormal immune reactions in the kidney or elsewhere in the body and which are responsible for over half the cases of terminal renal failure in the U.S. I am pleased to report that recently an antigen of the kidney glomerulus implicated in one of these disorders has been characterized and a "monoclonal" antibody against it has been successfully synthesized.

Concurrently, we are supporting a broad research effort in renal transplantation, on the causes for transplant rejection, and on improved immunosuppression. I am pleased to report that in renal transplantation, patient survival and functional kidney graft survival continue to improve due to a variety of recent research advances encompassing: 1) the "conditioning" of recipients with multiple blood transfusions or donor blood transfusions, and,
2) additional/new immunosuppressive agents such as cyclosporine, antilymphocyte- and antithymocyte globulin, and "monoclonal" antibodies.

As a culmination of many years of Institute research sponsorship, formation and recurrence of certain kidney stones, if due to excessive absorption of dietary calcium, can now be inhibited and prevented by the newly FDA-approved drug sodium cellulose phosphate--a so-called "orphan drug"--which binds calcium in the intestine and prevents its absorption.

Massive magnesium ammonium phosphate ("struvite") stones which account for 15-20 percent of all kidney stones are particularly serious since they are usually too massive to be passed through the urinary system and the impact on the affected kidneys is severe. Based on Institute-supported studies the FDA has recently approved another preventive "orphan drug," acetohydroxamic acid, which can prevent the sequence of events that lead to formation of struvite stones.

"Factor VIII" is a plasma component without which blood cannot clot. Administration of this factor is a vital necessity for the functioning and survival of hemophiliac patients, who cannot produce it themselves. The current cost of preparing the natural factor is prohibitive and equally serious is the risk of contracting hepatitis (almost 100%). The genes for Factor VIII have now been isolated and production, through recombinant DNA techniques, of artificial Factor VIII is near and promises to transform the quality of life of thousands of hemophiliac patients.

Research Training. The development of a well-trained, highly qualified cadre of biomedical researchers is the most important ingredient of a productive research effort. Without such scientists and their original ideas, the accomplishments I have mentioned would not have been possible, we would not be able to capitalize upon the unprecedented scientific opportunities which now exist nor could we adequately pursue future developments. The key to future advances in biomedicine and to improved health for our Nation lies in todays training of tomorrow's researchers. The Fiscal Year 1985 budget request proposes support for 838 trainees.

I would like to say that the remarkable research advances and unprecedented scientific opportunities in the areas of science for which this Institute is responsible, of which I have cited only a few examples, have created a sense of great optimism and expectation within the NIADDK and the scientific community. It is an exciting time to be a part of the NIH and this country's biomedical research program. The budget request for 1985 is $475,324,000, an increase of $12,750,000 over the comparable 1984 level. Mr. Chairman, I shall be happy to answer any questions you may have.

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## Biography of Dr. Lester B. Salans

POSITION: Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

EDUCATION:
B.A., University of Michigan, 1957
M.D., University of Illinois, College of Medicine, 1961

EXPERIENCE:
Director, NIADDK, 1982-present
Acting Director, NIADDK, 1981-1982
Associate Director, Diabetes, Endocrinology and Metabolic Diseases, 1976-1982
Chief, Cellular Metabolism and Obesity Laboratory, NIADDK, 1977-1982
Professor Adjunct, Dartmouth Medical School, 1978-present
Associate Professor, Dartmouth Medical School, 1971-1978
Head, Section of Endocrinology and Metabolism, Dartmouth Hitchcock Medical Center, 1968-1976
Chief Medical Resident, The Hospital of The Rockefeller University, 1967-1968
Fellow, National Institutes of Health Special Fellowship, The Rockefeller University, 1966
Post-doctoral Fellow in Endocrinology and Metabolism, Stanford University Medical Center, 1964-1966
Internship and Residency Training, Internal Medicine, Stanford University Medical Center, 1961-1964

RESEARCH INTEREST AND EXPERIENCE: Diabetes and obesity, mechanism of insulin action, intermediary metabolism

ASSOCIATION MEMBERSHIPS:

American Association for the Advancement of Science
American Diabetes Association
American Federation for Clinical Research
American Society of Clinical Investigation
Endocrine Society
Fellow, American College of Nutrition
Fellow, Council on Atherosclerosis, American Health Association
New York Academy of Sciences
Sigma Xi

**EDITORIAL BOARDS AND JOURNAL REVIEWS:**

American Journal of Nutrition
American Journal of Physiology
Diabetes
Endocrinology
Journal of Clinical Endocrinology and Metabolism
Journal of Clinical Investigation
Journal of Lipid Research
Metabolism
Science

**SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS:**

Phi Eta Sigma, University of Michigan, 1954
Alpha Omega Alpha, University of Illinois, College of Medicine, 1959
Mosby Scholarship Award, University of Illinois, College of Medicine, 1961
M.D., cum laude, University of Illinois, College of Medicine, 1961
Distinguished Public Service Award, Juvenile Diabetes Foundation, 1979
National Institutes of Health Director's Award, 1980
Senior Executive Service Performance Bonus, 1981, 1982, 1983
Author of more than 50 publications on diabetes, metabolism and obesity

## BUDGET IMPACTS

Senator WEICKER. Dr. Salans, in terms of budget, where does it impact on you and what are the most critical impacts, in terms of what won't be done?

Dr. SALANS. The budget heavily impacts on the Institute and the science and scientists it supports in the country in several places. Let me cite some specific examples. In the first place, under this budget, the Institute will fund 109 fewer new and competing research project grants in 1985 than it will in 1984, and many fewer than we have during each of the last 5 years. Therefore, many excellent established scientists will be lost and our ability to support new ideas diminished. In addition to that, we are going to have to reduce the direct costs in support of each of those grants by 13 percent, and the direct costs of each noncompeting research grant by 5 percent. Moreover, we will have to reduce the support of our research centers by 19 percent, and we will be reducing the number of trainees and career awards that we make in 1985 by close to 100.

Those are the facts. The impact will, at best, be to slow the rate of progress, and reduce the scope of the science that our Institute is responsible for.

Senator WEICKER. As I referred to in my opening statement, we were excited to learn recently that a scientist at Rutgers University may have isolated a virus that causes rheumatoid arthritis. Are you familiar with that?

Dr. SALANS. Yes; in a recent article that appeared in the March 30, 1984, issue of the Journal of Science, several collaborating scientists reported on a study in which a virus was isolated from the joints of patients with rheumatoid arthritis. That virus appears to be a member of the parvovirus family and has been given the specific name, RA–1. When these researchers injected this virus into the brains of mice, as a means of maintaining the virus, they induced a variety of abnormalities in the mice including crippling. They did not describe inflammation of the joints or arthritis, but a crippling of the joints.

The most potentially promising part of the study stems from the fact that they then proceeded to make an antibody to the virus and tested that antibody in tissues obtained from joints of patients with rheumatoid and other forms of arthritis. They found that the joint material obtained from the overwhelming majority of those with rheumatoid arthritis possessed a viral antigen which reacted with the antibody, whereas this was not the case in joint materials obtained from the patients who did not have rheumatoid arthritis. They, therefore, concluded that there might be some relationship between this parvovirus and rheumatoid arthritis. The researchers emphasized that a cause and effect relationship was by no means established and additional research is needed.

Thus, whether this is a cause of rheumatoid arthritis remains uncertain. Infectious agents have for some time been considered as possible causes of rheumatoid arthritis. This provides, I think, a lead in this area for scientists to follow in the future.

Senator WEICKER. You are currently running a clinical trial on close control of blood gluocose in diabetics. What is the status of the trial and what do you hope to find out?

Dr. SALANS. Well, it's proceeding very nicely. The protocol has been developed and approximately 250 patients have been recruited into the first phase of the trial, which is a feasibility study. Those patients will soon have certain baseline characteristics assessed and then they will be randomized into either an intensively treated group, the experimental treatment group or a conventionally treated control group, and will be followed for about 2 years. We believe that this feasibility study will soon begin, and that within 2 years we will have some information about whether the very demanding, ambitious and costly study that we have planned for the long term is possible and desirable.

I hope within 2 years to report to you our progress on this study.

Senator WEICKER. I have—there are other questions for response to the record.

I think that I might use this occasion to bring this up. I think it is also fair for me as committee chairman to give my opinion as to where we sit on the various budget proposals before the Congress and why it is a matter of deep concern to me, personally, as well as it is to other members of the committee. What we're grappling with here are proposals that, in fact, cap all the education and health science funding, where there is, probably, a need for somewhere around 8 percent real growth. And these, I might add, are the problems that we're running into. We are talking about this covering a 3-year period.

Yes; over a 3-year period. So I think you can see what the ramifications are in terms of all your various institutes and NIH overall. It's obviously an unacceptable proposal, as far as I'm concerned. And to give you an idea of what happened just from 1980 to 1984, defense spending outlays expanded roughly from $133 to $260 billion, and discretionary areas of education and science under the limited jursdiction of this committee, have gone from $33 to $22 billion. Now that's going to tell you something about what we're going to end up with.

And then when you add to that all of the proposals for the next 3 years, an 8-percent growth for defense and zero for everybody else, I think the bottom line is going to be devastating.

So I don't mind saying in the course of this public hearing that those who believe that the work of the various institutes is important and NIH itself, they better have their voices heard. It's just not enough for a few of us to feel as we do. I think the Nation, as a whole, ought to know what's at stake.

Is it true, Dr. Wyngaarden, while I've got you here—and this is a generalization, but I'd like to know how close to the truth it is, that for every dollar spent on biomedical research, you get approximately $13 in savings in health care costs, or if it is not, would you like to refine it a little bit?

Dr. WYNGAARDEN. That's approximately correct. In Dr. Mushkin's report, which looked at the economic benefits of health research from 1900 to 1975, the raw figure for that time, according to her econometric analysis, was about 13 to 1. A dollar value was placed on the additional use of productive work according to standard economic principles.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. OK. Dr. Salans. Thank you. Thank you very much. There will be other questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: The guidelines provided to NIH along with the allocation were very specific and in general these guidelines were applied to each of the institutes, however, we were able to negotiate a small change in allocated number of new and competing research project grants but the funds to support these 20 grants had to be taken from research centers. We also had some flexibility in the distribution of funds between intramural research, research and development contracts, and research career awards.

Question: To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer: Each new and competing regular research grant award will be reduced by approximately 13 percent from the projected recommended level. Since grantees tend to protect personnel as much as possible, most of this cut would be taken in supplies and materials categories. With an estimated cut of over 30 percent in supplies and materials we are very concerned about the viability of the research projects but cannot point to delays in specific program areas since this will effect all of them.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84? What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: While we will maintain the same number of centers as in 1984, each will be reduced by 19 percent. We have no way to assess the impact of this magnitude of cut, but we expect that it will be necessary to terminate or slow some of the individual projects within each center.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on you area of biomedical research in the future?

Answer: This institute will be able to support 838 trainees in 1985 which is 77 fewer than the 915 supported in 1984. This means that at sometime in the future, there could be about 8 percent fewer reseach investigators which were trained with federal support than if we continued the program at the current level.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: To maintain the same number of new and competing research grants and centers with the same rates of direct cost reductions, the same number of trainees and research and development contracts, and the same levels of intramural research effort and administrative support in 1985 as in 1984 would require approximately $45.6 million over the current budget request.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Our share of this reduction is 30. Because our administrative and support functions are already efficient (about 3.5 percent of our budget in 1984), we will have to take nearly all of this reduction in intramural research. Hopefully, only the scope and not the quality of the research will be effected.

## THE GRANTS ROLLER COASTER

Question: It looks to me like your Institute has been on a new grants roller coaster for the last four or five years. We understand that back in 1981 your number of new and competing grants was at 759.

1982 - 645
1983 - 777
1984 - 756
1985 - 647 projected.

How do you account for this inconsistency? Too many new grants leading to too many continuations, and so forth?

Answer: Within the overall funds available and the guidelines provided to it, NIH could allocate only 647 to this institute.

Question: How will the fall-off of 109 grants between fiscal 1984 and 1985 affect your scientific momentum?

Answer: We estimate that 52 fewer current investigators will not continue to be supported and that 57 fewer new researchers or current researchers with new project plans will be funded than in 1984. Particularly with M.D.'s it is unlikely that once they leave research for other careers they will return so this is a potential permanent loss.

Question: To what extent have you been stretching dollars to keep the number of new grants as high as possible?

Answer: In 1982, we reduced each research grant by 3 1/2 percent and each center by 7 percent. In 1983, we reduced research grants and centers an average of 6 percent. This year, 1984, we are reducing non-competing research grants by 4 percent, competing research grants by 7 percent and centers by 6 percent.

## NEW ARTHRITIS DISCOVERY

Question: We were recently excited to learn that a scientist at Rutgers University may have isolated a virus that could be the cause of rheumatoid arthritis. According to the reports, the virus may be a member of the parvovirus family. How significant is this discovery?

Answer: The March 30, 1984, issue of the journal, Science, reports the isolation of a virus that may be the cause of rheumatoid arthritis. The discovery of what is called the "RA-1" virus is certainly a promising one. Thus far, however, only a small number of rheumatoid arthritis patients have been studied. Of 14 tissue specimens taken from rheumatoid arthritis patients, 13 showed evidence of the virus, while all specimens from osteoarthritis patients were negative. It should also be noted that although the researchers report that this virus appears to produce a crippling of the limbs and other symptoms when injected into the brains of young mice, the authors do not indicate that arthritis -- that is, inflammation of the joints -- occurred in the animals. It is possible that the RA-1 virus may prove to be a causative agent in rheumatoid arthritis, but as the authors themselves acknowledge, there is a yet undefined link with this disease. Clearly, more research is needed to fully explore these early findings.

Question: What possibility is there that this research could lead to development of a preventive vaccine?

Answer: Diseases caused by viruses are amenable to prevention through vaccination and, in fact, research has already conquered many infectious diseases through exactly this means. Additional research needs to be conducted, however, to determine if the newly identified virus is indeed the causative agent in rheumatoid arthritis; to attempt to determine what subsets of the population might be at risk for this viral infection; and to develop and test a vaccine against the virus, first in animals and then -- if feasible and desirable -- in research patients. This process can require intensive investigation over a long period of time.

Question: What role, if any, did the Arthritis Institute play in the work that led up to the discovery?

Answer: The research leading to the discovery of the RA-1 virus, as reported in Science, was supported by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; the National Institute of Allergy and Infectious Diseases; the Kroc Foundation, and Arthritis Foundation, and the Charles and Johanna Busch Foundation of Rutgers University. The researchers are affiliated with the Waksman Institute of Microbiology at Rutgers University; the Montefiore Hospital, Albert Einstein College of Medicine, and Eli Lily and Company.

Question: Will the new development result in any change of focus or increase of funding of research in the arthritis field?

Answer: It is too early to know what effect this discovery will have on arthritis research. Often a discovery of this nature in a given field attracts talented investigators who seek to confirm and exploit the new findings. It is possible, therefore, that we will see more research applications on infectious causes of arthritis and more applications dealing either with genetic factors that may predispose to viral infections or immune abnormalities that may result from a viral infection. Research applications of high scientific merit and technical feasibility will draw resources to a particular line of inquiry through the NIH competitive peer review process.

## DIABETES CLINICAL TRIAL

Question: I believe you currently are running a clinical trial on close control of blood glucose in diabetes.

Answer: Patient recruitment has just been completed for Phase I, the feasibility study which is expected to last about two years.

This study is designed to determine (1) whether a clinically and statistically significant difference can be achieved between treatment groups; (2) whether patient compliance, safety, and relative utility of the regimens are at acceptable levels; (3) if the progression of symptoms associated with patients' diabetes can be measured with sufficient accuracy.

Question. Are there any indications yet as to whether tight control of blood glucose helps prevent the complications of diabetes?

Answer: This clinical trial is designed to determine the effect of close control of blood glucose level in ameloriating the long-term complications of diabetes. The feasibility study will only determine whether such a trial can be conducted safely with a reasonable probability of answering that basic question. The full-scale trial would then be intitiated, probably in 1986. We do not expect any of the complications will be totally eliminated and that only at the end of a seven to ten year period will we be able to identify any significant differences between close-control of blood glucose levels and other currently standard treatment regimens.

Question: What decisions do you need to make to go into a full-scale trial on the matter?

Answer: An independent policy advisory group will review the results of the feasibility study and make a recommendation to the Institute as to whether the full-scale Diabetes Control and Complications Trial should be initiated. This recommendation will be based upon the degree of success in each of the areas I have just outlined for you.

Question: How many people, how much money and how much time would be required by a full-scale trial?

Answer: The full-scale trial would last for seven to ten years at a cost of between $60 million and $80 million and will involve about 1,000 patients.

## DIGESTIVE DISEASES "SPLIT"

Question: Last year there was a bit of dust-up about funding of a digestive diseases initiative that included centers, a clearinghouse and a data collection effort. The question was whether you would put more money into these activities or more money, as directed by the Senate, into restoring Administrative cuts in new and continuation research grants. Where did you finally come out on this matter?

Answer: Since the instructions of the Senate and the House of Representatives were somewhat different, we allocated the funds to provide about 60% of the digestive diseases earmark and about 50% of the differences between the two recommendations for increasing new and competing research grants.

Question: How much additional money will go into the digestive disease effort?

Answer: $3 million has been allocated for at least 5 new digestive disease centers and $500 thousand will be available for the data collection and clearinghouse.

## GALLSTONES

Question: About 20 million people in the United States have gallstones and one million new cases are identified each year. The medical approaches to gallstones could be surgical or use of drugs to dissolve them. Which is preferable?

Answer: Surgical treatment is the preferable treatment for gallstones in those patients who are good surgical risks, or who could not follow a program of treatment of drugs regularly and consistently for the months that are usually necessary. In patients who are poor surgical risks, a trial of drug treatment can be worthwhile.

Question: What risks would there be in using drugs to get rid of gallstones -- and what about recurrence?

Answer: The drug presently used to treat gallstones, chenodeoxycholic acid, occasionally can cause damage to the liver. However, this evidence of damage usually clears up when the patient discontinues the drug. There is also evidence that this drug may be associated with an increase in blood cholesterol. This could become a factor in predisposing to arteriosclerosis, particuarly if it is a result of continued use of the drug.

It is common for gallstones to recur when treatment is stopped after they have been dissolved with chenodeoxycholic acid and it has not been clearly shown;that this recurrence can be prevented by the continuation of small doses after the gallstones have been dissolved. If gallstones recur, medical treatment can be tried again in an effort to dissolve the recurrent stones.

## LIVER TRANSPLANTS

Question: Last year, an NIH Census Development Conference recommended more frequent use of liver transplants of which about 75 to 100 are performed annually in the United States. Has the conference recommendation resulted in any policy change on liver transplants by your Institute?

Answer: As in the past, the Institute continues to encourage research on liver transplantation itself and in areas that will aid transplantation efforts, such as organ preservation. For example, NIADDK has supported the research of Dr. Thomas Starzl, a leader in the field of liver transplantation, for over 20 years.

Recommendations of the conference concerning research are consistent with the Institute's ongoing activities. Recommendations of the conference regarding the broader application of liver transplantation as a therapeutic modality in certain forms of liver disease are being considered by other components of the Department, such as the Health Care Financing Administration, which are concerned with issues surrounding the delivery of health care services.

Question: Have any resources been re-allocated as a result?

Answer: The Institute is pursuing three new initiatives relevant to liver transplantation largely as a result of broad consultation with and the recommendations of scientific advisors in the digestive diseases community. In January 1984, the Institute published a program announcement encouraging research applications on liver transplantation and liver diseases. This is a trans-NIH initiative involving the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, the National Institute of Child Health and Development and the National Institute of General Medical Sciences. In February, the Institute announced the issuance of a Request for Proposal for a liver transplanation data base for the collection and analysis of research data in this field. In March, we published a Request for Application for research on organ preservation.

## RESEARCH ISSUES

Question: There are more than 100 types of arthritis and related diseases which afflict millions of Americans. Rheumatoid arthritis is a particularly debilitating form of the disease. What investigations currently are planned or under way to test the use of irradiation treatments in easing the symptoms of intractable rheumatoid arthritis?

Answer: The Institute is currently supporting research on the use of irradiation of the lymph nodes -- or total lympoid irradiation -- as a therapeutic approach to rheumatoid arthritis that is unresponsive to conventional therapies. Studies have shown that this type of irradiation can reduce joint inflammation in severe rheumatoid arthritis, refractory to all other forms of treatment, by normalizing the ratio of white cells that suppress immune responses of white cells that promote immune responses.

Question: Are any hazards associated with the use of this treatment?

Answer: Irradiation is a potent therapeutic approach and carries with it the possibility of undesirable side effects. We know that irradiation can in itself cause cancer, so use of irradiation therapy requires careful monitoring of both level and frequency of exposure. Since the immune system is affected by this therapy, great care must be exercised to guard against a weakening of the body's defenses against infectious agents and possibly other types of diseases.

Question: What is the status of your research on osteoporosis? Are you having any success with the uses of calcium, fluoride and/or vitamin D in this effort?

Answer: In Fiscal Year 1983, the Institute's extramural support of research on osteoporosis was approximately $1.8 million. This research includes studies of:

- Bone change, pre- and postmenopause, in approximately 200 women, longitudinally, from age 35.
- Effects of exercise on bone density in postmenopausal women.
- Possible regenerative effects of electrical pulse stimulation in bone thinning or crushed vertebrae in osteoporosis.
- Effects of fluoride therapy in a clinical trial involving approximately 400 postmenopausal osteoporosis patients, all of whom are receiving calcium supplementation.

With respect to combating osteoporosis, calcium is highly recommended prophylactically and as a treatment. Studies to date have also suggested estrogen, fluoride, exercise, and calcitriol (a metabolite of vitamin D) as therapeutic modalities in osteoporosis. The Institute is sponsoring a Consensus Development Conference April 2-4, 1984, to review the state of the science in osteoporosis and to make recommendations regarding effective clinical management of this disease.

Question: What success are you having with the use of nutritional therapy as a means of delaying progression of chronic renal disease?

Answer: Nutrition has long been known to be an important factor in the management of kidney disease, particularly end stage renal disease, and the Institute has historically supported research in this area. Increases in our knowledge about nutrition and kidney disease have recently enabled the Institute to develop, with the advice of the research community, a major new initiative for a controlled multicenter clinical trial to assess the effect of dietary modification on the progression of chronic renal disease. NIADDK published solicitations for the cooperative clinical study and for the necessary data coordinating center in September 1983 and January 1984, respectively. The Institute has received 28 research applications in response to the first solicitation. These underwent initial review in April and will be considered by the NIADDK Advisory Council in May. Responses to the solicitation for the data coordinating center are due in May and will be reviewed this summer. The Institute expects to begin the full initiative in FY 1984.

As the Committee is aware, end stage renal disease is a major public health problem, with Federal expenditures for dialysis and kidney transplantations totaling an estimated $2 billion annually under the Medicare Program of the Health Care Financing Administration (HCFA). The NIADDK initiative has been developed in close consultation with the Office of the Assistant Secretary for Health and other Departmental components and represents a collaborative effort between NIH and HCFA.

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## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

Question: Dr. Salans, your report on mycoplasma-related causes of rheumatoid arthritis referred to a 1971 study indicating that tetracycline use produced no significant benefits.

Dr. Loe's prepared testimony referred to the use of tetracycline in the treatment of severe gum disease. The testimony reads as follows: "Not only does the drug attack bacteria implicated in the disease, but it also reduces elevated levels of tissue collagenase, an enzyme that destroys collagen -- the basic building block of the connective tissues, ligaments and bones that support teeth."

If tetracycline retards the destructive process of this enzyme in the supporting tissue of the teeth, why wouldn't it have some efficacious effect in retarding the action of synovial collagenase in the joints of an arthritis patient?

Answer: The potential infectious etiology of arthritis is one of several lines of research supported by the Institute. Possible infectious agents include bacteria, viruses, and other micro-organisms such as mycoplasma. NIADDK recently asked the National Arthritis Advisory Board (NAAB) to review the state of the science in mycoplasma research and to make recommendations in this regard. The ensuing report of an expert panel of Board members noted that mycoplasmas may play a role in rheumatoid arthritis and recommended a laboratory study in which joint tissue samples from 100 rheumatoid and 100 nonrheumatoid arthritis patients be analyzed for evidence of mycoplasmas using the most up-to-date technology available. The panel also suggested that, if the biopsy study yields positive results in sufficiently large number of rheumatoid arthritis patients, that a specific double-blind controlled clinical trial be conducted of antimycoplasma (antibiotic) therapy in mycoplasma-positive patients. According to the panel, this two-study sequence, "will be the only way to link antimycoplasma therapy with efficacy in the complex and heterogeneous disease that is rheumatoid arthritis." NIADDK is making plans to encourage research interest in the sequential investigations recommended by NAAB panel members in their report on mycoplasmas and arthritis.

### PROJECT CONTRACTS

Question: Dr. Salans, last year's budget estimated an expenditure of $10,905,000 on project contracts in fiscal year 1984. Your current estimate has fallen to about $10 million. Can you tell us how you were able to save $903,000 in this area?

Answer: The $903 thousand you refer to was for a clinical trial in kidney diseases. Since this trial will now be done with research grants the funds were transferred to that mechanism.

Question: Your equipment budget for fiscal year 1984 was set at $1.6 million in last year's justifications. Your current estimate is $3,083,000. Why did you decide on an increase of this magnitude?

Answer: This is the amount we need to primarily replace obsolete equipment in our intramural research program and to acquire some new items needed to stay current with the increasingly sophisticated methodologies of modern science. In 1982, with an actual decrease in the budget, we spent only $654 thousand in this area and fell far behind our normal replacement plan. In 1983, we spent $2.9 million which helped to catch up somewhat and our current estimate of $3.1 million for 1984 will also enable some additional catching up in our modernization efforts. The original estimate for 1984 was based on an overall 3.4 percent increase for the institute and major reductions in each research grant and center were proposed, the intramural research program was also severely restricted. The appropriation provided by the Congress was much to our projected requirements in all areas and we will be able to provide this higher amount for equipment modernization and updating.

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## QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

### DIABETES RESEARCH

Question: I have two areas of questioning relating to diabetes research. What priority do you assign to epidemiological research on diabetes?

Answer: Since it appears that a number of pathogenic mechanisms may give rise to diabetes, information is essential on the number of people affected by, and on the characteristics of the population potentially predisposed to, diabetes. Only through major epidemiolgical studies are investigators able to examine and evaluate all of the factors hypothetically associated with diabetes and to judge with statistical confidence the relationship of these factors to the disease. Applications to conduct studies in this area are reviewed through the Institute's peer review system, and the Institute eagerly welcomes and encourages applications for such research.

Question: How many research grants did you fund last year relating to the epidemiology of diabetes?

Answer: In FY 1983, the NIADDK supported 12 research grants at a total funding level of $2,177,000.

In addition, the Institute also supported the National Diabetes Data Group, authorized by Congress in 1980. Concerns of the National Diabetes Data Group include defining data needs, coordinating the collection of data from multiple sources, standardizing collection procedures and terminology, making reliable data available to users, and measuring the medical and socioeconomic impact of diabetes. The Data Group consists of epidemiologists, representatives of Federal and voluntary-sector organization, and experts in the research, nutritional, and socioeconomic aspects of diabetes. It is the data group's mission to establish, in concert with the National Diabetes Information Clearinghouse (NDIC), "a system for the collection, storage, analysis, retrieval, and dissemination of data concerning diabetes, including, where possible, data involving general populations for the purpose of detecting individuals with a risk of developing diabetes." Through its data collection and analysis activities, the data group serves as a central source for the accurate statistics that are essential to national development of scientific priorities and public health program plans.

NIADDK also supports, within its Intramural Research Program, a field station in Phoenix, Arizona, which is the site of long term epidemiological studies of diabetes, arthritis and other chronic diseases in the inhabitans of the Gila River Reservation. The major studies being undertaken involve diabetes mellitus, of which the inhabitants of the Gila River Reservation have the highest frequency in the world. One-half of those aged 35 years and over have diabetes! The NIADDK investigations include examinations during pregnancy and at the time of birth, and then longitudinal follow-up of all of the population, at biennial intervals, whenever possible, to determine the determinants and natural history of diabetes and its various complications.

Question: Is this an area that deserves more attention and, if so, what kind of studies do you feel are needed?

Answer: Epidemiological research is fundamental to an understanding of the risk factors associated with diabetes. Only through well-designed epidemiologic studies can scientists determine whether diabetes has a genetic, environmental, cultural, gender-related, age-related, or race-related relationship.

Since the Naitonal Commission on Diabetes delivered its report to Congress in 1975, NIADDK has expanded its support of epidemiologic studies on diabetes as a complement to the clinical and basic research we support on this disease. We now fund epidemiologic studies on the etiology, natural history, and development of diabetic complications in several populations. These include insulin-dependent diabetics in Allegheny County, Pennsylvania, southern Wisconsin, and Colorado; Mexican-Americans in Starr County, Texas, and colorado; adult Caucasions in Rancho Bernardo, California; American Indians in Arizona and Oklahoma; Japanese-Americans in Seattle, Washington; and Polynesians, Melanesians, and Micronesians in the Pacific islands. However, there are other populations that would potentially be very informative to study. One of these is Hawaiians. The characteristics of diabetes in Japanese-Americans living in Hawaii would be interesting to compare to our current study on the Seattle Japanese-Americans; persons of Polynesian decent living in Hawaii would provide the same informative comparison group for our studies on Pacific Islanders. A second population would be a total community in the U.S. in which we could develop a prospective study of actors which are antecedent to the development of diabetes, and which could be intervened in to prevent the development of diabetes, very much as our colleagues in the cardiovascular field have done in Framingham, Massachusetts. Yet a third project would be a prospective in which to conduct this study is the siblings of insulin-dependent diabetics, whom we now know are at especially high risk for the development of diabetes. A fourth population, that would prove to be very informative in determining the relative influence of genetic and environmental factors in causing diabetes, is identical twins. I understand that the Veterans Adminstration, in collaboration with the National Academy of Sciences, is now mounting a registry of identical twins, and we would certainly want to take advantage of this registry for the purpose of research on diabetes.

Question: On the matter of geographical distribution, many small medical schools feel the NIH research grants seem to go to the big states on either coast rather than to the small institutions in the small states. Could you please supply the committee a list or a map showing in which states west of the Mississippi River and east of California diabetes research grants were awarded last year?

Answer: The requested list follows.

# 1983 DIABETES RESEARCH GRANTS AWARDED TO INSTITUTIONS WEST OF THE MISSISSIPPI RIVER (EXCLUDING CALIFORNIA)

| GRANT NUMBER | INVESTIGATOR | | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|---|
| ARIZONA | | | | |
| 5 F32 AM 06936-02 | PELTON, JOHN T | | UNIVERSITY OF ARIZONA | 22,716 |
| 2 R01 AM 21085-07 | HRUBY, VICTOR J | | UNIVERSITY OF ARIZONA | 111,654 |
| 5 R23 AM 28313-03 | KORC, MURRAY | | UNIVERSITY OF ARIZONA | 41,994 |
| | | INSTITUTION TOTAL | 3 | 176,364 |
| | | STATE TOTAL | 3 | 176,364 |
| COLORADO | | | | |
| 5 F32 AM 06982-02 | WHITE, ALAN R | | UNIVERSITY OF COLORADO AT BOULDER | 17,736 |
| | | INSTITUTION TOTAL | 1 | 17,736 |
| 5 F32 AM 06838-02 | GARVEY, WILLIAM T | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 20,040 |
| 1 F32 AM 07116-01 | KERN, PHILIP A | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 20,040 |
| 5 T32 AM 07446-02 | ROBERTSON, R PAUL | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 43,972 |
| 5 R01 AM 25241-06 | OLEFSKY, JERROLD M | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 24,922 |
| 5 R01 AM 26180-05 | OLEFSKY, JERROLD M | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 8,318 |
| 3 R01 AM 26356-03S1 | ECKEL, ROBERT H | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 8,989 |
| 2 R01 AM 26356-04 | ECKEL, ROBERT H | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 44,843 |
| 5 R01 AM 27887-03 | CRAPO, PHYLLIS A | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 13,669 |
| 5 R01 AM 28353-03 | MALLER, JAMES L | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 55,761 |
| 5 R23 AM 29981-02 | MARSHALL, STEPHEN | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 15,509 |
| 1 R01 AM 30747-01A1 | HAMMAN, RICHARD F | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 422,532 |
| 5 R23 AM 31072-03 | BERHANU, PAULOS | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 36,075 |
| 5 R01 AM 31112-02 | METZ, STEWART A | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 67,808 |
| 5 R01 AM 31317-02 | KOLTERMAN, ORVILLE G | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 4,679 |
| 1 R01 AM 32493-01 | HAMMAN, RICHARD F | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 131,282 |
| 1 R01 AM 32880-01 | BERHANU, PAULOS | | UNIVERSITY OF COLORADO HLTH SCIENCES CTR | 71,579 |
| | | INSTITUTION TOTAL | 16 | 990,018 |
| | | STATE TOTAL | 17 | 1,007,754 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| IDAHO | | | |
| 5 R01 AM 20035-06 | RITTER, ROBERT C | UNIVERSITY OF IDAHO | 49,656 |
| | INSTITUTION TOTAL | 1 | 49,656 |
| | STATE TOTAL | 1 | 49,656 |
| IOWA | | | |
| 5 R01 AM 28615-03 | KAPLAN, MURRAY L | IOWA STATE UNIVERSITY OF SCIENCE & TECH | 60,804 |
| | INSTITUTION TOTAL | 1 | 60,804 |
| 2 T32 AM 07018-10 | GRANNER, DARYL K | UNIVERSITY OF IOWA | 105,190 |
| 1 F32 AM 07125-01 | HELD, DOUGLAS D | UNIVERSITY OF IOWA | 17,736 |
| 1 F32 AM 07212-01 | KOEPKE, KATHLEEN | UNIVERSITY OF IOWA | 17,040 |
| 5 R01 AM 20858-06 | GRANNER, DARYL K | UNIVERSITY OF IOWA | 97,435 |
| 3 R01 AM 24037-05S1 | GRANNER, DARYL K | UNIVERSITY OF IOWA | 20,198 |
| 5 P30 AM 25295-05 | GRANNER, DARYL K | UNIVERSITY OF IOWA | 593,305 |
| 5 R01 AM 25421-05 | BAR, ROBERT S | UNIVERSITY OF IOWA | 81,448 |
| 5 R23 AM 27744-02 | SANDRA, ALEXANDER | UNIVERSITY OF IOWA | 39,051 |
| 5 R01 AM 28516-03 | SPECTOR, ARTHUR A | UNIVERSITY OF IOWA | 63,402 |
| 5 U01 AM 30659-02 | SCHROTT, HELMUT G | UNIVERSITY OF IOWA | 206,804 |
| 1 R23 AM 31464-01A1 | HOLMES, CLARISSA S | UNIVERSITY OF IOWA | 45,211 |
| | INSTITUTION TOTAL | 11 | 1,286,820 |
| | STATE TOTAL | 12 | 1,347,624 |
| KANSAS | | | |
| 5 R01 AM 09072-19 | KIMMEL, JOE R | UNIVERSITY OF KANSAS COL HLTH SCI & HOSP | 82,128 |
| 5 R01 AM 18381-10 | HUDSON, BILLY G | UNIVERSITY OF KANSAS COL HLTH SCI & HOSP | 97,017 |
| 5 R01 AM 21169-06 | HUDSON, BILLY G | UNIVERSITY OF KANSAS COL HLTH SCI & HOSP | 54,460 |
| 5 R01 AM 26191-04 | KIMMEL, JOE R | UNIVERSITY OF KANSAS COL HLTH SCI & HOSP | 52,940 |
| 5 R01 AM 27660-04 | BUNAG, RUBEN D | UNIVERSITY OF KANSAS COL HLTH SCI & HOSP | 44,702 |
| | INSTITUTION TOTAL | 5 | 331,247 |
| 5 R01 AM 21672-07 | DENTLER, WILLIAM L, JR | UNIVERSITY OF KANSAS LAWRENCE | 81,127 |
| | INSTITUTION TOTAL | 1 | 81,127 |
| | STATE TOTAL | 6 | 412,374 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| LOUISIANA | | | |
| 1 R01 AM 31676-01 | CHANG, SIMON H | LOUISIANA STATE UNIV A&M COL BATON ROUGE | 78,528 |
| | INSTITUTION TOTAL | 1 | 78,528 |
| 2 R01 AM 18370-09 | COY, DAVID H | TULANE UNIVERSITY OF LOUISIANA | 66,124 |
| 5 R01 AM 30167-02 | COY, DAVID H | TULANE UNIVERSITY OF LOUISIANA | 71,113 |
| | INSTITUTION TOTAL | 2 | 137,237 |
| | STATE TOTAL | 3 | 215,765 |
| MINNESOTA | | | |
| 5 T32 AM 07352-05 | GERICH, JOHN E | MAYO FOUNDATION | 80,013 |
| 2 R01 AM 20411-07 | GERICH, JOHN E | MAYO FOUNDATION | 214,507 |
| 5 R01 AM 20973-06 | SERVICE, F JOHN | MAYO FOUNDATION | 94,528 |
| 2 R01 AM 26989-04 | HAYMOND, MOREY W | MAYO FOUNDATION | 211,277 |
| 5 R01 AM 29953-02 | RIZZA, ROBERT A | MAYO FOUNDATION | 129,233 |
| 5 U01 AM 30609-02 | SERVICE, F JOHN | MAYO FOUNDATION | 249,473 |
| | INSTITUTION TOTAL | 6 | 979,031 |
| 5 U01 AM 30598-02 | ETZWILER, DONNELL D | ST. LOUIS PARK MEDICAL CENTER | 187,350 |
| | INSTITUTION TOTAL | 1 | 187,350 |
| 5 K08 AM 01014-02 | CHAVERS, BLANCHE M | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 53,190 |
| 1 K01 AM 01157-01 | KLEIN, DAVID J | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 44,636 |
| 1 F32 AM 07187-01 | GORES, PAUL F | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 19,236 |
| 5 T32 AM 07196-08 | SORENSON, ROBERT L | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 37,331 |
| 5 T32 AM 07203-07 | OPPENHEIMER, JACK H | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 64,952 |
| 5 R01 AM 17697-10 | BROWN, DAVID M | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 170,889 |
| 5 R01 AM 19269-08 | SUTHERLAND, DAVID E | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 83,440 |
| 5 R01 AM 19764-07 | HENDERSON, LA VELL M | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 62,547 |
| 2 R01 AM 20729-06A1 | BARBOSA, JOSE J | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 149,266 |
| 3 R01 AM 20742-05S1 | BARBOSA, JOSE J | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 34,115 |
| 2 R01 AM 20742-06 | BARBOSA, JOSE J | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 113,725 |
| 5 R01 AM 22182-05 | HAMILTON, DAVID W | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 93,486 |
| 5 R01 AM 23001-06 | PLAGEMANN, PETER G | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 86,516 |
| 5 R01 AM 30072-02 | BUCHWALD, HENRY | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 178,019 |
| 5 R01 AM 30519-02 | SHERIDAN, JUDSON D | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 74,594 |
| 5 U01 AM 30626-02 | BARBOSA, JOSE J | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 193,091 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| 1 R01 AM 31342-01 | SEGALL, MIRIAM | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 63,877 |
| 1 R01 AM 32237-01 | HEGRE, ORION D | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 77,111 |
| 1 R01 AM 32660-01 | FURCHT, LEO T | UNIVERSITY OF MINNESOTA OF MNPLS-ST PAUL | 103,958 |
|  | INSTITUTION TOTAL | 19 | 1,703,979 |
|  | STATE TOTAL | 26 | 2,870,360 |

MISSOURI

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| 5 U01 AM 30590-02 | GOLDSTEIN, DAVID E | UNIVERSITY OF MISSOURI COLUMBIA | 222,606 |
|  | INSTITUTION TOTAL | 1 | 222,606 |
| 5 R01 AM 01226-27 | LACY, PAUL E | WASHINGTON UNIVERSITY | 161,976 |
| 2 R01 AM 03373-24A1 | MC DANIEL, MICHAEL L | WASHINGTON UNIVERSITY | 85,943 |
| 5 R01 AM 06181-22 | MC DANIEL, MICHAEL L | WASHINGTON UNIVERSITY | 169,178 |
| 5 F32 AM 06841-02 | EVELHOCH, JEFFREY L | WASHINGTON UNIVERSITY | 18,468 |
| 3 F32 AM 07011-01S1 | CONSTABLE, STEFAN H | WASHINGTON UNIVERSITY | 660 |
| 5 T32 AM 07120-09 | DAUGHADAY, WILLIAM H | WASHINGTON UNIVERSITY | 168,087 |
| 1 F32 AM 07155-01 | CHRISTENSEN, RAYMOND L | WASHINGTON UNIVERSITY | 17,736 |
| 5 R01 AM 16746-11 | PERMUTT, MARSHALL A | WASHINGTON UNIVERSITY | 113,424 |
| 5 R01 AM 18986-08 | HOLLOSZY, JOHN O | WASHINGTON UNIVERSITY | 82,011 |
| 5 R01 AM 19645-06 | SCHMIDT, ROBERT E | WASHINGTON UNIVERSITY | 71,028 |
| 2 P60 AM 20579-06 | DAUGHADAY, WILLIAM H | WASHINGTON UNIVERSITY | 1,567,405 |
| 5 R01 AM 21966-06 | SCHARP, DAVID W | WASHINGTON UNIVERSITY | 141,128 |
| 5 R01 AM 25585-05 | SCHARP, DAVID W | WASHINGTON UNIVERSITY | 105,225 |
| 5 R01 AM 25897-05 | MC DONALD, JAY M | WASHINGTON UNIVERSITY | 99,850 |
| 5 R01 AM 25909-05 | GINGERICH, RONALD L | WASHINGTON UNIVERSITY | 63,520 |
| 5 R01 AM 26806-02 | CHIRGWIN, JOHN M | WASHINGTON UNIVERSITY | 57,297 |
| 5 R01 AM 27085-04 | CRYER, PHILIP E | WASHINGTON UNIVERSITY | 147,862 |
| 5 R01 AM 28042-03 | BALDASSARE, JOSEPH J | WASHINGTON UNIVERSITY | 62,302 |
| 5 R01 AM 28312-03 | LAWRENCE, JOHN C, JR | WASHINGTON UNIVERSITY | 61,763 |
| 5 U01 AM 30653-02 | SANTIAGO, JULIO V | WASHINGTON UNIVERSITY | 226,590 |
| 5 R23 AM 31496-02 | LUSTMAN, PATRICK J | WASHINGTON UNIVERSITY | 53,793 |
| 1 R01 AM 31866-01 | PERMUTT, MARSHALL A | WASHINGTON UNIVERSITY | 129,051 |
| 7 R01 AM 33446-01 | GONEN, BOAS | WASHINGTON UNIVERSITY | 95,140 |
|  | INSTITUTION TOTAL | 23 | 3,699,437 |
|  | STATE TOTAL | 24 | 3,922,043 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| NEW MEXICO | | | |
| 5 R01 AM 25132-04 | EATON, R PHILIP | UNIVERSITY OF NEW MEXICO ALBUQUERQUE | 351,416 |
| 1 R01 AM 31973-01 | SCHADE, DAVID S | UNIVERSITY OF NEW MEXICO ALBUQUERQUE | 130,658 |
| | INSTITUTION TOTAL | 2 | 482,074 |
| | STATE TOTAL | 2 | 482,074 |
| NORTH DAKOTA | | | |
| 5 R01 AM 28318-03 | GLASGOW, RUSSELL E | NORTH DAKOTA STATE UNIVERSITY | 92,498 |
| | INSTITUTION TOTAL | 1 | 92,498 |
| 5 R01 AM 07141-21 | NORDLIE, ROBERT C | UNIVERSITY OF NORTH DAKOTA | 90,770 |
| | INSTITUTION TOTAL | 1 | 90,770 |
| | STATE TOTAL | 2 | 183,268 |
| OKLAHOMA | | | |
| 5 K01 AM 00891-04 | DONALDSON, DAVID L | UNIVERSITY OF OKLAHOMA HLTH SCIENCES CTR | 61,290 |
| | INSTITUTION TOTAL | 1 | 61,290 |
| | STATE TOTAL | 1 | 61,290 |
| OREGON | | | |
| 3 R01 AM 21982-03S1 | HOWARD, CHARLES F, JR | MEDICAL RESEARCH FOUNDATION OF OREGON | 10,323 |
| 2 R01 AM 21982-04A1 | HOWARD, CHARLES F, JR | MEDICAL RESEARCH FOUNDATION OF OREGON | 90,274 |
| | INSTITUTION TOTAL | 2 | 100,597 |
| 5 T32 AM 07331-05 | GREER, MONTE A | OREGON HEALTH SCIENCES UNIVERSITY | 51,236 |
| 5 R01 AM 25703-05 | HARE, JAMES F | OREGON HEALTH SCIENCES UNIVERSITY | 43,229 |
| | INSTITUTION TOTAL | 2 | 94,465 |
| 5 R01 AM 31031-02 | WILSON, WILLETTA | OREGON RESEARCH INSTITUTE | 157,506 |
| | INSTITUTION TOTAL | 1 | 157,506 |
| | STATE TOTAL | 5 | 352,568 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| TEXAS | | | |
| 5 K08 AM 01024-02 | REDWINE, WILLIAM A | BAYLOR COLLEGE OF MEDICINE | 52,666 |
| 1 F32 AM 07138-01 | D'AGOSTINO, JOBETH L | BAYLOR COLLEGE OF MEDICINE | 17,736 |
| 5 T32 AM 07348-05 | FIELD, JAMES B | BAYLOR COLLEGE OF MEDICINE | 78,212 |
| 5 R01 AM 17978-08 | NELSON, THOMAS E | BAYLOR COLLEGE OF MEDICINE | 112,964 |
| 3 R01 AM 19318-06S1 | BIRNBAUMER, LUTZ | BAYLOR COLLEGE OF MEDICINE | 22,367 |
| 2 R01 AM 19318-07 | BIRNBAUMER, LUTZ | BAYLOR COLLEGE OF MEDICINE | 80,947 |
| 5 R01 AM 25253-05 | FIELD, JAMES B | BAYLOR COLLEGE OF MEDICINE | 102,573 |
| 5 R01 AM 26498-04 | CHAN, LAWRENCE C | BAYLOR COLLEGE OF MEDICINE | 94,366 |
| 5 P30 AM 27685-02 | FIELD, JAMES B | BAYLOR COLLEGE OF MEDICINE | 456,164 |
| | INSTITUTION TOTAL | 9 | 1,017,995 |
| 5 R01 AM 14638-13 | GRACY, ROBERT W | NORTH TEXAS STATE UNIVERSITY | 89,979 |
| | INSTITUTION TOTAL | 1 | 89,979 |
| 5 R23 AM 31418-02 | CIMADEVILLA, JOSE M | ST. MARY'S UNIVERSITY OF SAN ANTONIO | 43,383 |
| | INSTITUTION TOTAL | 1 | 43,383 |
| 5 R01 AM 19891-06 | GUNN, J MARTYN | TEXAS AGRI AND MECH UNIV COLLEGE STATION | 74,743 |
| | INSTITUTION TOTAL | 1 | 74,743 |
| 5 R01 AM 26432-03 | DYCKES, DOUGLAS F | UNIVERSITY OF HOUSTON AT HOUSTON | 41,835 |
| 5 R01 AM 30577-02 | EICHBERG, JOSEPH | UNIVERSITY OF HOUSTON AT HOUSTON | 67,356 |
| | INSTITUTION TOTAL | 2 | 109,191 |
| 3 R01 AM 16947-09S1 | SHERRY, ALLAN D | UNIVERSITY OF TEXAS DALLAS | 44,705 |
| | INSTITUTION TOTAL | 1 | 44,705 |
| 2 R01 AM 02700-24 | UNGER, ROGER H | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 78,522 |
| 2 T32 AM 07307-06 | FOSTER, DANIEL W | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 130,144 |
| 5 R01 AM 16194-12 | UYEDA, KOSAKU | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 85,409 |
| 5 R01 AM 18573-22 | FOSTER, DANIEL W | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 197,896 |
| 2 R01 AM 21163-04A2 | FAWCETT, C PETER | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 88,783 |
| 5 R01 AM 22150-05 | HELDERMAN, J HAROLD | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 99,800 |
| 5 R01 AM 29717-03 | REED, BRENT C | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 68,653 |
| 5 U01 AM 30611-02 | RASKIN, PHILIP | UNIVERSITY OF TEXAS HLTH SCI CTR DALLAS | 240,534 |
| | INSTITUTION TOTAL | 8 | 989,741 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| TEXAS | | | |
| 5 T32 AM 07282-06 | LAVIS, VICTOR R | UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON | 60,363 |
| 5 R01 AM 27885-03 | FERRELL, ROBERT E | UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON | 36,331 |
| 1 R23 AM 32895-01 | HANIS, CRAIG L | UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON | 29,550 |
| | INSTITUTION TOTAL | 3 | 126,244 |
| 3 R01 AM 19473-07S1 | OLSON, MERLE S | UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT | 11,054 |
| 2 R01 AM 19473-08A1 | OLSON, MERLE S | UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT | 85,697 |
| 5 R01 AM 29797-03 | WARD, WALTER F | UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT | 47,211 |
| | INSTITUTION TOTAL | 3 | 143,962 |
| 5 R23 AM 26644-03 | STUART, CHARLES A | UNIVERSITY OF TEXAS MED BR GALVESTON | 46,471 |
| | INSTITUTION TOTAL | 1 | 46,471 |
| 1 F32 AM 07091-01 | WHITE, JAMES W | UNIVERSITY OF TEXAS SYSTEM CANCER CENTER | 17,736 |
| | INSTITUTION TOTAL | 1 | 17,736 |
| | STATE TOTAL | 31 | 2,764,150 |
| UTAH | | | |
| 5 R01 AM 32261-02 | WINDER, WILLIAM W | BRIGHAM YOUNG UNIVERSITY | 47,032 |
| | INSTITUTION TOTAL | 1 | 47,032 |
| 5 R01 AM 27929-03 | KIM, SUNG-WAN | UNIVERSITY OF UTAH | 80,864 |
| | INSTITUTION TOTAL | 1 | 80,864 |
| | STATE TOTAL | 2 | 127,896 |

| GRANT NUMBER | INVESTIGATOR | INSTITUTION | ENCUMBERED AMOUNT |
|---|---|---|---|
| WASHINGTON | | | |
| 5 K04 AM 00682-04 | DE HAEN, CHRISTOPH A | UNIVERSITY OF WASHINGTON | 38,345 |
| 1 K08 AM 01194-01 | BEARD, JAMES C | UNIVERSITY OF WASHINGTON | 53,190 |
| 5 P01 AM 02456-25 | BIERMAN, EDWIN L | UNIVERSITY OF WASHINGTON | 638,152 |
| 5 F32 AM 06983-02 | FIGLEWICZ, DIANNE P | UNIVERSITY OF WASHINGTON | 18,468 |
| 5 T32 AM 07247-07 | BIERMAN, EDWIN L | UNIVERSITY OF WASHINGTON | 99,497 |
| 5 R01 AM 12829-15 | PORTE, DANIEL, JR | UNIVERSITY OF WASHINGTON | 138,763 |
| 5 P30 AM 17047-09 | PORTE, DANIEL, JR | UNIVERSITY OF WASHINGTON | 809,407 |
| 5 R01 AM 17844-09 | WOODS, STEPHEN C | UNIVERSITY OF WASHINGTON | 92,352 |
| 3 R01 AM 27267-03S1 | DE HAEN, CHRISTOPH A | UNIVERSITY OF WASHINGTON | 26,176 |
| 5 R01 AM 27954-03 | GORDON, MICHAEL J | UNIVERSITY OF WASHINGTON | 134,153 |
| 5 R01 AM 28180-03 | SCHUFFLER, MICHAEL D | UNIVERSITY OF WASHINGTON | 93,906 |
| 5 R23 AM 28382-02 | PAQUETTE, THOMAS L | UNIVERSITY OF WASHINGTON | 35,388 |
| 1 R01 AM 29816-01A1 | COOK, DANIEL L | UNIVERSITY OF WASHINGTON | 51,708 |
| 5 U01 AM 30604-02 | PALMER, JERRY P | UNIVERSITY OF WASHINGTON | 176,811 |
| 1 R01 AM 30770-01A1 | HORBETT, THOMAS A | UNIVERSITY OF WASHINGTON | 91,252 |
| 5 R01 AM 30780-02 | PALMER, JERRY P | UNIVERSITY OF WASHINGTON | 69,736 |
| 5 R01 AM 30992-02 | GOODNER, CHARLES J | UNIVERSITY OF WASHINGTON | 101,878 |
| 1 R01 AM 31170-01 | FUJIMOTO, WILFRED Y | UNIVERSITY OF WASHINGTON | 222,147 |
| | INSTITUTION TOTAL | 18 | 2,891,329 |
| 5 R01 AM 28087-03 | RITTER, WILMA S | WASHINGTON STATE UNIVERSITY | 73,931 |
| | INSTITUTION TOTAL | 1 | 73,931 |
| | STATE TOTAL | 19 | 2,965,260 |

SOURCE: SPIB, OPPA, NIADDK (SPEC. REPORT # 8435B)

## NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

**STATEMENT OF DR. KATHERINE BICK REPRESENTING DR. MURRAY GOLDSTEIN, DIRECTOR**

**ACCOMPANIED BY:**

**WILLIAM MATTHEWS, BUDGET OFFICER**

**DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. Next we'll have the National Institute of Neurological and Communicative Disorders and Stroke. The budget request for the Institute is $344.6 million and that's only $9 million above the fiscal 1984 appropriation.

Here to present the Institute's request is Dr. Katherine Bick. I understand Dr. Goldstein is ill, I hope not seriously so. Welcome, Doctor.

Dr. BICK. Thank you, Mr. Chairman.

I'd like to introduce, before I begin, Mr. William Matthews, Budget Officer for the Institute.

[The statement follows:]

## STATEMENT OF DR. MURRAY GOLDSTEIN

Today I am pleased to report to you recent advances and new opportunities in our nation's battle against the devastation caused by diseases of the brain and nervous system. This has been a time of great achievement, of significant growth in our knowledge of the brain and the nervous system in health and in disease. These accomplishments and the opportunity for even greater accomplishments to come have been documented by a panel of twenty-five eminent scientists, each a nationally known expert who reviewed recent scientific accomplishments and research opportunities in the neurosciences and communicative sciences. These illustrious scientists have written of great achievement in the neurosciences in recent years. We are on the cusp of breakthroughs in many different diseases and in our basic understanding of the brain. The experts tell us that the opportunity is available in our lifetime to understand how the brain works; to put substance into the concept of the mind; to uncover the secrets of memory and to heal the brain damaged by developmental defects, trauma, disease or aging.

Research is crucially significant because every disease that attacks the nervous system is serious; no part of the nervous system can be lost or damaged without major disability. Neurological disorders attack people of all ages, starting with the young born with spina bifida, Tay-Sachs disease, muscular dystrophy, cerebral palsy, or neurofibromatosis. Neurological disorders also strike adults in the prime of life, perhaps with multiple sclerosis, Huntington's disease, amyotrophic lateral sclerosis (ALS), myasthenia gravis or head or spinal cord injuries. Others, such as Parkinson's disease, tinnitus, Alzheimer's disease, and stroke, attack the older citizen, while some disorders, like epilepsy and a wide variety of hearing disorders, can occur at any time in life. Only a few of these disorders are now curable. Many lead to death, but only after long years of failing abilities. In most cases, we cannot yet modify or slow the course of the disease. However, this disheartening recital of the consequences of neurological and communicative disease is only a prelude to the opportunities for research advances now possible for the first time.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is currently supporting research on all of these diseases, research that is directly relevant to the approximately 600 discrete neurological and communicative disorders.

## Genetic Disorders

Two exciting research accomplishments have been achieved in the area of genetic disorders of the nervous system. Scientists, in our Institute and elsewhere, have been cracking the code of life and gaining new abilities to diagnose neurological diseases before they occur.

Huntington's Disease: Late in the fall of 1983, NINCDS grantees led by Dr. James Gusella, discovered a marker that lies close to the gene for Huntington's disease on chromosome 4. Huntington's disease is a fatal inherited disorder with no known cure. Each child of a parent with Huntington's disease has a 50 percent chance of getting the disease; but the disease does not strike until middle age, often after he or she has had children. The newly discovered genetic marker is the first step toward developing a test to identify carriers of Huntington's disease before symptoms appear.

The discovery is exciting for another reason as well. The actual mutant gene in Huntington's disease is in close proximity to this marker, in the same segment of the same chromosome. Now we can focus our research to a segment of a particular chromosome. Once we find the gene defect, we will be closer to understanding how the gene produces this devastating disease.

In addition to helping Huntington's disease families, this discovery may eventually aid families with other inherited neurological diseases, such as familial Alzheimer's disease, neurofibromatosis, and tuberous sclerosis. The research strategy of building a large family pedigree, then using recombinant DNA technology to locate a gene marker offers great hope.

Gaucher's Disease: Gaucher's disease, like Tay-Sachs and Fabry's diseases, is a genetic disorder that results in an enzyme deficiency which causes a harmful build-up of fatty compounds called lipids in brain and body cells. Gaucher's disease is the most prevalent Jewish inherited disease, affecting approximately 10,000 Americans.

The NINCDS Intramural Research Program has recently developed an experimental enzyme replacement therapy for Gaucher's disease patients. These scientists have also identified and cloned the gene for the enzyme which is defective in this disease. Cloning of the gene permits scientists to produce the large quantities of the enzyme needed for replacement therapy. The knowledge of the location of the Gaucher's gene will be used to develop a test for diagnosis of the disease before symptoms and damage occur. The same NINCDS scientists are trying to clone the gene for Tay-Sachs and the other lipid storage diseases in order to develop therapies for these diseases.

## Alzheimer's Disease

Alzheimer's disease is one of the most disturbing diseases we study because its patients literally cease to be themselves. The disease affects over one million Americans.

There are two major ideas about the origin of the damage seen in the brain in Alzheimer's disease. One possibility is that the disease is caused by an unusual communicable agent which kills the cells in the outer mantle of the brain. These dead cells lead to the formation of the tangles and plaques in the brain that are characteristic of the disease. Other research implies that the disease is caused by something that kills the nerve cells in the basal area of the brain, deep in the interior section. The death of the nerve cells there causes the visible changes in the cortex. We do not know which idea, if either, is accurate and are following up both hypotheses in research funded by the Institute. When we discover the origin of Alzheimer's disease, we will be on the road to developing an effective treatment.

## Central Nervous System Implants

Brain implants are an area of research of great excitement. We are born with all the nerve cells we will ever have. Implants of nerve cells into a damaged brain offer a promising method for restoring function lost through disease, injury, or genetic disorder. While implants in the brain and the central nervous sytem were previously not successful, new techniques offer great hope.

In several different animals, transplants have been shown to alleviate functional disorders induced by lesions in the spinal cord or brain. Scientists have used the implant technique successfully in rats with a form of Parkinsonism. The "thinking cap" or frontal cortex of rats was the site of another set of experiments. In this trial, the rats with the correct implant to repair a cortex lesion learned how to run a maze in approximately the same time as normal rats, while rats with lesions and no implants required far more time to learn this behavior.

The technique has recently been applied in humans. Swedish researchers have used an implant technique developed by an NINCDS grantee to implant adrenal medulla cells in patients with Parkinson's disease. While the results to date have been mixed, the approach is promising. The implications of brain implant experimentation are significant. Perhaps in the future, scientists will replace damaged spinal cord cells with undamaged cells and paralysis will be cured. Perhaps areas of the brain devastated by stroke or Parkinson's disease will again function.

## The Neuron

Our understanding of basic neuroscience and neurobiology has greatly expanded in the past decade. We used to envision a neuron as a simple wire that transmitted an electric current. It had "plugs" at either end, one to produce and send the current and the other to receive it. Now we acknowledge the complexity of the neuron, the building block of the nervous system. We know that the neuron can be considered not only as an electrical wire but also as a chemical factory. It produces neurotransmitters, among them neuropeptides, and transports them from the nerve cell body to the ends of the axons, which may be as much as three feet away where they, through the synapses, affect the receptors on the next nerve or muscle.

Neuropeptides and other neurotransmitters are the chemicals that help send the messages through the neuron and from one neuron to another. We have now identified more than 30 neurotransmitters, each with a very specific purpose, and are learning more each year. While nerve cells were once thought to use only one neurotransmitter, we now know they can secrete more than one and that the balance amongst them is important.

We can use this new, more complex idea of the neuron to pinpoint what goes wrong in a specific neurological disease. For example, when receptor errors occur, the nerve impulse is not received. In myasthenia gravis, the receptor for acetylcholine, a critical neurotransmitter, does not make the proper connection and muscle weakness, including paralysis, results. Transport errors also cause disease; amyotrophic lateral sclerosis (ALS) is an example where the neurotransmitter may not reach the receptors and a transport problem is hypothesized. The defects in the diseases of protein synthesis, still another category, can be visualized in the nerve cell body. Neurogenetic disorders are in this group, including the lipid storage diseases, neurofibromatosis, Huntington's disease, and tuberous sclerosis. Yet another class of diseases affects the nerve cell body by selective cell death. In these diseases, something kills the nerve cell body and, eventually, the entire nerve dies. Sometimes, as in Alzheimer's disease, cells in a particular region of the brain die. In other cases, nerve cells that produce a particular neurotransmitter are attacked. Parkinson's disease with its dopamine neurotransmitter is an example of this latter type of disease. In some disorders, we do not yet know exactly where the difficulty begins. For example, sensorineural hearing loss may be a receptor disorder or it may be a case of selective cell death. Multiple sclerosis might be considered a disease of the support system cells of the neuron. In MS, the myelin or white fatty substance surrounding the nerve sheath hardens and scars. The impulse is not transmitted effectively from the cell body to the receptors.

Our greater understanding of the neuron and its complexity opens up a new universe of research possibilities. We know so much more now than we did 20 years ago. Yet there are so many questions still to ask and so much more to learn. If neuroscience research continues its current pace, we should soon have a broader and deeper knowledge of nerve cell communication, of how the brain and central nervous system function, as well as of therapies for neurological disorders that are now considered incurable. The future in neuroscience research will be even more vital and exciting than the present.

## Senator Jacob Javits Neuroscience Awards

In the Conference Report for the Fiscal Year 1984 budget, the Congress required the NINCDS to establish the Senator Jacob Javits Neuroscience Awards. We are grateful to the Congress for creating these awards and are certain that they will be very productive. The Javits Awards, I am pleased to announce, have been established and are being used to increase our understanding of the central nervous system in health and in disease. The first set of these awards has now been made and they are providing long-term stability to the most outstanding neuroscientists in the United States.

Our budget request for FY 1985 is $344,601,000, an increase of $9,404,000 over the comparable 1984 level.

I am pleased to present this information on the newest neurological and communicative science advances to you today, and will answer any questions you may have.

## BIOGRAPHY OF DR. MURRAY GOLDSTEIN

| | |
|---|---|
| POSITION: | Director, National Institute of Neurological and Communicative Disorders and Stroke |
| BIRTHPLACE & DATE: | New York, New York; October 13, 1925 |
| EDUCATION: | B.A., New York University, 1947<br>D.O., Des Moines Still College of Osteopathic Medicine, 1950<br>M.P.H., University of California, School of Public Health, 1959 |
| EXPERIENCE: | Director, NINCDS, 1982-present<br>Acting Director, NINCDS, 1981-1982<br>Deputy Director, NINCDS, 1978-1981<br>Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present<br>Director, Stroke and Trauma Program, NINCDS, 1976-1978<br>Director, Extramural Programs, NINCDS, 1961-1976<br>Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968<br>Chief, Special Projects Branch, NINCDS, 1960-1961<br>Assistant Chief, Research Grants Review Branch, DRG, 1959-1960<br>Acting Chief, Section on Virus Diseases of the CNS, Bureau of Acute Communicable Disease, California State Department of Public Health, 1958<br>Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958<br>Assistant Chief, Grants and Training Branch, NHI, 1953-1958 |
| ASSOCIATION MEMBERSHIPS: | American Academy of Neurology<br>American Association for the Advancement of Science<br>American Heart Association, Council on Stroke<br>American Neurological Association<br>American Osteopathic Association<br>Association for Research in Nervous and Mental Disease<br>Member, Board of Directors, John P. Robarts Research Institute, London, Ontario, Canada (1983-1987)<br>Society for Neuroscience<br>The American Parkinson Disease Association, Medical Advisory Board<br>Eisenhower Institute for Stroke Research<br>United Cerebral Palsy Research & Educational Foundation Board of Directors<br>Consultant (Neurology), Pan American Health Association<br>Consultant, World Health Organization Program on Neurosciences<br>World Federation of Neurology |

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|---|---|
| | International Brain Research Organization<br>Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine |
| SPECIAL AWARDS, CITATIONS, OR PUBLICATIONS: | Beta Alpha Epsilon; Biology National Honor Society, NYU<br>Psi Chi; Psychology National Honor Society, NYU<br>Sigmi Alpha; Osteopathic Scholarship National Honor Society; College of Osteopathic Medicine<br>Delta Omega; Public Health National Honor Society; University of California<br>Doctor of Science (Hon); Kirksville College of Osteopathic Medicine<br>Doctor of Laws (Hon); New York Institute of Technology<br>Certificate of Merit; American Neurological Association<br>2nd Vice President; American Neurological Association<br>Silver Star; Purple Heart, U.S. Army<br>Meritorious Service Medal; Public Health Service<br>Distinguished Service Medal; U.S. Public Health Service<br>Founders Day Medal (S.S. Still Medal); University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa<br>Associate Editor, Stroke, A Journal of Cerebral Circulation, American Heart Association<br>Editorial Board, Osteopathic Annals<br>Editorial Board, International Journal of Neurology<br>Editorial Board, The Journal of Neuroepidemiology<br>Author of over 25 scientific papers and monographs |

## BIOGRAPHY OF DR. KATHERINE L. BICK

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|---|---|
| POSITION: | Deputy Director, NINCDS |
| BIRTHPLACE & DATE: | Charlottetown, Prince Edward Island, Canada<br>May 3, 1932 |
| EDUCATION: | B.S., (summa cum laude) Acadia University Wolfville, Nova Scotia, Canada 1951<br>M.S., Acadia University, Wolfville, N.S., Canada, 1952<br>Ph.D., Brown University, Providence, R.I., 1957 |
| EXPERIENCE: | Deputy Director, National Institute of Neurological and Communicative Disorders and Stroke, September 4, 1983 - present<br>Acting Deputy Director, NINCDS February 1, 1981 - September 3, 1983<br>Acting Associate Director for Neurological Disorders, November 24, 1982 - present<br>Deputy Director, Neurological Disorders Program, NINCDS, June 1979 - February 1981<br>Assistant Director, NDP, NINCDS, June 1977 - June 1979 |

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|---|---|
| | Health Scientist Administrator, NDP, NINCDS, May 1976 - June 1977<br>Assistant Professor, Department of Biology, Georgetown University, Washington, D.C. Member of the Graduate Faculty, The Graduate School, September 1970 - May 1976<br>Assistant Professor, Department of Biology, San Fernando Valley State College, Northridge, California, September 1961 - June 1966<br>Assistant Research Pathologist, Department of Pathology, UCLA School of Medicine, Los Angeles, California, January 1959 - August 1961<br>Research Associate, Collip Medical Research Laboratory, University of Western Ontario, Canada, September 1952 - August 1954 |
| ASSOCIATION MEMBERSHIPS: | American Neurological Association<br>American Academy of Neurology<br>Society of the Sigma Xi<br>American Association for the Advancement of Science<br>American Society of Zoologists<br>Association for Research in Nervous and Mental Disease<br>International Brain Research Organization |
| SPECIAL AWARDS, CITATIONS OR PUBLICATIONS: | National Research Council (Canada) Bursar, 1951 - 1952<br>Universal Match Foundation Fellow, 1956 - 1957<br>Federal Executive Institute Leadership Program, 1980<br>NIH Director's Award, 1977<br>Author of a number of scientific articles.<br>Editor of two books. |

## SUMMARY STATEMENT

Dr. BICK. I am pleased to have the opportunity to present to you and the subcommittee a brief summary of the impressive accomplishments and exciting opportunities that the recent decade of support for neuroscience research has provided for the Nation.

As we have learned to prevent death in infancy and to prolong life in maturity, as a nation we have turned to concern for the quality of life, not just how long people live. We, in the Neurology Institute, ask what can be more important to the quality of life than to be able to think, to be able to remember, to perceive, to communicate, and to be in command of our bodies and who we are.

Or to put it even more succinctly; to be a person; to have a brain that permits us to know who we are; to be able to cherish those about us; and to strive to excel in order to achieve our dreams. In fact, to be what all of us think when we think of being a human being.

To accomplish this the Congress has provided resources to the NINCDS to train the needed scientists, to establish the essential laboratories, and to discover the basic knowledge necessary for our great exploration of the frontiers of brain science. Many times in the past several years this has been called truly our last frontier.

Mr. Chairman, I'm pleased to report that this investment of our national resources has been successful, even beyond our expectations. Not just we, who see the results of the labors of the scientists, are excited, but you can read in almost any journal in the popular press and watch on television the excitement inspired by the ability to move into what has been called inner space; the frontiers of understanding human activity.

I will briefly talk about about some examples of advances which have taken place in the last year. The first of these has been the discovery, supported both by NINCDS and by our colleagues in the National Institute of General Medical Sciences, of a marker for the gene which causes Huntington's disease.

This is important, of course, for our understanding of Huntington's disease, but it is even more important when we consider that this is the application of the new techniques of molecular biology and recombinant DNA to the study of a devastating human disease of which we had very little knowledge.

In addition to what it can mean for Huntington's disease, it lets us know that this technique can be used to look at other very difficult problems. In Huntington's disease, let me remind you, sir, we do not know what goes wrong.

We had no idea until this work was begun on what chromosome the Huntington's disease gene was located. We now know that it is on chromosome 4 and we have a pretty good idea of the zip code on chromosome 4. What we're honing in on now is to find the house number. This landmark accomplishment opens the door to accomplishments in other neurogenetic diseases—neurofibromatosis, some forms of epilepsy, perhaps some kinds of Alzheimer's disease; a whole range of very difficult problems which we hope to be able to explore.

I would be remiss, I think, however, if I did not tell you that we have many more problems yet to solve. We have learned a great deal in the last 20 years about how the nerve cells function, but we have a great deal more to learn. We have learned that nerve cells function not only as electrophysiological conduits but also as complex metabolic factories with elaborate internal controls.

We have done a lot of dissecting apart of the nervous system and we are now, I hope, ready to go back and try to put it together. R.R. Bensley said, many years ago, that it didn't take much of a fool to take a watch apart, but it took a craftsman with a great deal of skill to put it back together so it would keep time.

In neuroscience, in neurobiology we're getting better at taking the nervous system apart, but we have a long way to go in learning how to put it back together again, to put all of what makes us human into an understanding that will not only help us deal with our everyday problems but to deal with the devastating problems of neurological disease.

Dr. Goldstein's written statement provides the subcommittee with detailed information which will elaborate on these points. Our goals are how to prevent, and when we fail to prevent, how to treat those disorders which affect the brain.

I would be pleased to answer any questions that the subcommittee may have.

### BUDGET IMPACT

Senator WEICKER. Where does the budget most harshly impact your Institute?

Dr. BICK. The President's budget proposal for 1985 would require a decrease in the number of new research grants to be funded. There would also be an impact on the number of new individuals who will be trained to carry forward our attack on the problems of the nervous system.

Research and development contracts would also be affected. We would not be able to provide for the establishment of any new specialized clinical research centers.

### THE JAVITS AWARDS

Senator WEICKER. In its fiscal 1984 bill, Congress specifically directed that $10 million of your appropriation be set aside for special scientific awards in honor of our former colleague, Senator Jacob Javits. I know that Dr. Goldstein spent a good deal of time on the project.

I might add that I was also pleased to hear that one of the first awards has gone to Dr. Kent Morest at the University of Connecticut Health Center.

Dr. Bick, would you bring us up to date on how this new program is progressing? How much money do you plan to invest in the Javits scholarships in fiscal 1985 and beyond?

Dr. BICK. Sir, as you know, the Javits Award Program was established in 1984 at the instigation of this committee. Thus far we have made 39 awards to extraordinarily distinguished neuroscientists throughout the Nation. Dr. Morest is a very excellent example of one such.

We expect to make another 25 or so awards at the conclusion of the meeting of our National Advisory Committee in late May. We, at the moment, would estimate that this would cost close to the $10 million which the committee directed us to spend.

It turns out that the average cost for the first year of these awards is $165,000. We have received a great many very touching letters from these 39 awardees expressing not only their gratitude to their colleagues in the scientific community who really made the selections, but also to the committee and to Senator Javits. It's been an extraordinarily rewarding experience.

For 1985 we have as yet no specific plans. At the pleasure of the Congress, we would hope to continue the program. In December, we convened an ad hoc advisory group to discuss with us how we might best approach the challenge presented to us by the Congress. We will provide a copy of the report for the record.

[The information follows:]

December 16, 1983

Director, NINCDS

Senator Jacob Javits Neuroscience Awards; Consultant Suggestions

National Advisory Neurological and Communicative Disorders and Stroke Council

The appropriation act for the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) for Fiscal Year 1984 assigned $10M for the initiation of Senator Jacob Javits neuroscience awards. On Tuesday, December 6, 1983, seven leaders in the neurological and communicative sciences met as consultants with the Director of NINCDS to discuss Institute scientific program activities that might be considered in order to implement the intent of the Congress (attachment I). Mrs. Marian Javits was present and participated in the discussion. The Institute's preliminary plan was used as background information and as a basis for initiating discussion (attachment II).

The consultants reviewed the intent of the Congress in making funds available for the Senator Javits awards and the several excellent opportunities these awards could provide for making substantive contributions to neuroscience research. It was emphasized that the single most important research resource that needed focused attention was people--the skilled investigator--both (a) junior investigators bringing new skills and new insights into neuroscience research and (b) already highly productive investigators who are leaders in exploring the new frontiers of neuroscience. The consultants agreed that NINCDS needs to initiate program activities that would provide additional opportunities to these two selected groups of neuroscientists of the greatest potential and productivity and that these activities should receive the highest priority for assistance through Senator Javits neuroscience awards.

In addition, the consultants felt consideration needed to be given to awarding program research grants to research groups for in-depth exploration of the emerging frontiers of neuroscience. Currently, molecular and cellular biology were suggested as excellent examples of neuroscience research areas deserving such consideration; however, it was also emphasized that flexibility was essential in order to take advantage later of future emerging research opportunities in other neuroscience and communicative science areas. Program research grant awards would fall within the broad scope of the present concept of NINCDS program-project grants but would provide broader degrees of scientific freedom to develop and pursue emerging concepts. They should not be as project bound as the present program-project grants format requires nor for as limited a period of time. Also discussed were: provision of additional training opportunities for basic scientists to understand clinical issues such as is presently done by means of the NINCDS Neurobiology of Disease Workshop grant to the Society for Neuroscience; acceleration of programs to meet the high priority need for the recruitment and establishment of clinician-scientists having both modern biological research skills and clinical expertise; the more vigorous use of existing grant and contract mechanisms for additional research emphasis to the application of newly reported basic scientific information to clinical problems deserving added attention (e.g., TRH in ALS); mechanisms to increase the number of M.D.-Ph.D trainees in the neurological and communicative sciences.

The consultant group recognized the strengths and importance of the NIH peer review process and stressed that any program activities initiated by the NINCDS as Senator Jacob Javits awards needed to be managed within the framework of that scientific review and selection process. It was also recognized that since some initiatives would probably require discussions to bring about changes in Departmental or NIH administrative procedures, they would require planning as more long range objectives; other initiatives not requiring such changes could be considered as immediate objectives. Finally, the group pointed out that the funds available in this fiscal year for this important thrust forward were limited and only a very few goals could be achieved at this time.

IT WAS EMPHASIZED BY ALL THAT THE SENATOR JACOB JAVITS NEUROSCIENCE AWARDS PROVIDE A UNIQUE OPPORTUNITY FOR SEMINAL CONTRIBUTIONS BOTH TO UNDERSTANDING THE BIOLOGY OF THE NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND TO PROVIDE FOR ADVANCES IN UNDERSTANDING HOW THE HUMAN BRAIN AND NERVOUS SYSTEM FUNCTION.

The following summarizes specific suggestions:

Immediate Objectives:

- Provide research project grant stability of support to a selected group of Senator Jacob Javits Neuroscience Investigators whose research makes fundamental contributions to an understanding of the neurological and communicative systems and their disorders. This would involve extending the period of research grant support to outstanding scientists to 5-7 years. (Ed. note: The present DHHS policies would have to be amended to provide for this.)

- Select a limited number of career development applicants of the very highest quality and potential in the basic and clinical sciences for designation as Senator Jacob Javits Neuroscience Scholars. Special emphasis should be given to the selection of young persons preparing for careers as clinician-scientists and planning to apply the concepts and techniques of the basic sciences to the problems of human pathology.

- Stimulate and support additional research activities which target both at the cell biology of the nervous system (including the communicative system) and at the application of this information to clinical problems of nervous system degeneration.

Long Term Objectives:

- Establish a research grant program of "Senator Jacob Javits Neuroscience Research Centers" in which multidisciplinary teams of the most capable scientists would address fundamental biological issues of nervous system structure and function. This would be a modification of the present NINCDS program-project activity but would provide for broader degrees of research freedom and for stability over longer periods of time. (Ed. note: The present NIH regulations and NINCDS procedures will have to be amended to provide for this.)

- Provide research grant as well as stipend support to those career development awardees in the neurological and communicative sciences designated as Senator Jacob Javits Neuroscience Scholars. The present system of NINCDS career development research awards provides only stipend support and does not provide for necessary research grant funds (an "associated research grant"). The addition of such research funds should be based upon review and recommendation by Council of the pending development award application. (Ed. note: This authority will require at the least a change in regulations and perhaps even an amendment to the legal authority of the NINCDS.)

The above consultant suggestions have been most helpful for Institute planning. If the major suggestions were implemented, the following budgetary needs over a 5 year period would have to be considered:

Budgetary Needs

| Awards | 5 Year Objective | Year 1 | Year 2 | Year 3 | Year 5 |
|---|---|---|---|---|---|
| Senator Javits Investigators | 150 Awards at $250,000 each (30 new awards each year) | $7.0M | $16M | $24M | $40M |
| Senator Javits Scholars | 100 Awards at $75,000 each (20 new awards each year) | $ .5M | $ 2M | $ 4M | $ 6.5M |
| Senator Javits Research Centers | 15 Awards over 3 years at $750,000 each | ---- | $ 5.25M | $13M | $15M |
| Special Research Studies | Research projects on premature death of cells; studies of therapy | $2.5M | $ 5.0M | $ 8M | $10M |

Institute plans for the Senator Jacob Javits neuroscience awards will be discussed by the Council Planning Committee at its meeting on January 25 and by the full Council at its meeting on January 26-27, 1984.

ATTACHMENT I

## JAVITS AWARD PROGRAM ADVISORY MEETING

**National Institute of Neurological and Communicative Disorders and Stroke**
**National Institutes of Health**
**Room 8A28, Building 31**

**December 6, 1983**
**9:30 a.m. - 12:00 noon**

**Members**

**Dr. William Maxwell Cowan**
**Professor and Vice President**
**The Salk Institute**
**(NANCDS Council Member)**

**Dr. Murray Goldstein**
**Director, National Institute of Neurological and Communicative Disorders and Stroke**

**Dr. Edward Kravitz**
**Professor**
**Department of Neurobiology**
**Harvard Medical School**

**Dr. Thomas W. Langfitt**
**Professor and Director**
**Department of Neurosurgery**
**University of Pennsylvania**
**School of Medicine**

**Dr. Guy H. McKhann**
**Professor and Chairman**
**Department of Neurology**
**The Johns Hopkins University**
**School of Medicine**
**(NANCDS Council Member)**

**Dr. Fred Plum**
**Professor and Chairman**
**Department of Neurology**
**Cornell University**
**Medical College**

**Dr. Robert J. Ruben**
**Professor of Otorhinolaryngology**
**Albert Einstein**
**College of Medicine**

**Dr. William D. Willis, Jr.**
**Professor, Anatomy and Physiology, and Chief, Comparative Neurobiology**
**Marine Biomedical Institute**
**University of Texas**
**Medical Branch, Galveston**
**(President-Elect; Society for Neuroscience)**

**Guests**

**Mrs. Marian Javits**

### INVESTIGATORS LONG-TERM STABLE SUPPORT

Dr. BICK. In addition to the provision of long-term stable support for investigators of the first rank, this NINCDS ad hoc committee recommended that we should look to the future and provide opportunities to train individuals so that they can become the neuroscience leaders of the 1990's, paying particular attention to the need for inspiring clinical investigation by young physicians to take on these tough problems of the nervous system.

They further discussed the idea that it would be very useful to provide a different kind of specialized research center, a center of excellence in which the very difficult long-range problems could be addressed. They envisaged this as the cutting edge of neuroscience; long-term provision of support without too many strings attached so that these really creative individuals could explore their best ideas without the constraints of the very specific format of the grant application.

### RESEARCH OPPORTUNITIES

Senator WEICKER. At the request of the Senate Appropriations Committee, your Institute has produced what I think may be a landmark evaluation of research opportunities in the field of neurological and communicative sciences.

Speaking of advances in our understanding of the functions of the healthy and diseased human nervous system, the report states, "We are on the verge of an important new revolution in medicine."

What does the report say specifically that you can accomplish, and how much of what the report suggests can be accomplished within your budget for fiscal 1985?

Dr. BICK. Almost all what the report says—and this report was written by the leading experts in the country; and in their opinion—it could be accomplished within the near foreseeable future.

Senator WEICKER. At what price?

Dr. BICK. The price that the consultants indicated would be a fiscal 1985 budget of $667.861 million.

Senator WEICKER. What do you think of that, Mr. Itteilag? How does that fit? [Laughter.]

Mr. ITTEILAG. It's obviously more than can be afforded under the circumstances.

### ALZHEIMER'S DISEASE

Senator WEICKER. All right.

Where do we sit vis-a-vis Alzheimer's disease? I notice that you're only projecting a $300,000 increase in your research funding. Is that because you're being constrained by budget limitations?

Would you ask for more? Can more be meaningfully used in that area, or do you feel you're all right?

Dr. BICK. The projection rate for funding of our approved research grants is 29.1 percent for fiscal year 1985. Research activity in Alzheimer's disease has expanded dramatically over the last several years, and the calibre of this research is at the front rank.

In this as in other areas we will be forced to select only the very best of these applications. The funding rate for Alzheimer's disease applications is projected to be the same as in other areas of our responsibility.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much, Dr. Bick. There are other questions for response to the record. I appreciate your testimony.

Please give our best to Dr. Goldstein.

Dr. BICK. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question. You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reductiuon in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer. General guidelines were provided by the OMB, DHHS and NIH and included such things as the funding of 5,000 competing grants for all of the NIH, 9,000 research trainees and maintenance of other program activities at the level for 1984. The specific elements for the Institute's budget were formulated within these guidelines established by the NIH.

Question. What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer. While the FY 1985 budget request for NINCDS will fund 30 fewer competing research project awards, overall the NINCDS will fund 36 more research project grants as compared to FY 1984, In addition, 12 fewer research career development grants, 46 fewer research trainees and 6 fewer research contracts. Other activities would remain at the FY 1984 level. The President's budget allows us to capitalize on many research opportunities.

Question. To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer. Despite the resulting decrease in the number of competitive awards, in order to provide essential funding to awarded projects, no downward negotiations are planned for noncompeting research project grants in fiscal year 1985. Also, the 1985 request assumes no downward negotiations in direct costs for new and competing research project grants for NINCDS. Reductions will be made in the number of competing projects in the areas of multiple sclerosis, epilepsy, stroke and spinal cord injury.

Question. With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84?

Answer. We expect to negotiate the costs of centers downward about 2.5 percent from the recommended levels. The resulting savings will permit us to fund the same number of centers as in 1984.

Question. What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer. As a consequence of fiscal constraints in the past two years, the Institute has negotiated with the centers to reduce the work effort and the amount awarded. These negotiations will continue in FY 1985 on an average of 2.5 percent from the recommended amounts. The effect of these reductions will be to defer some projects and to slow progress on others.

Question. The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer. It is very difficult to make quantitative estimates of research training needs in specific disciplines on an annual basis, but past experience has shown that research training needs are especially critical in the clinical research areas. The Institute, therefore, is emphasizing research training directed toward increasing the number of skilled research investigators with a background in clinical areas such as neurology, neurosurgery, otolaryngology, audiology and speech pathology. This will result in a decrease in the number of research training awards in the basic neurosciences.

Question. How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer. An increase of $9,754,000 would be required to maintain the same level of effort as in 1984.

Question. The Budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it?

Answer. The NINCDS share of the proposed personnel cut is 30 FTE's in fiscal year 1985. The proposed reduction will be made in other than permanent appointments. We are currently studying the situation to determine the exact positions to be affected. Every effort will be made to minimize its effect on the the scientific research staff.

Question. With what effect on research?

Answer. The most significant effect could occur in the Intramural Research Program. In other areas, the reductions would limit the staff who administer and monitor the Institute's grant and contract activities. This could have negative effects on the quality of the management of these extramural awards and on the monitoring of research results.

## RESEARCH OPPORTUNITIES AND NEEDS

Question. At the request of the Senate Appropriations Committee, your Institute has produced what I think may be a landmark evaluation of research opportunities in the field of neurological and communicative sciences. Speaking of advances in our understanding of the functions of the healthy and diseased human nervous system, the report states: "We are on the verge of an important new revolution in medicine." Dr. Goldstein, what does the report say specifically that we can accomplish if we only set our minds and our resources to the task?

Answer. The independent study and report, entitled, "An Evaluation of Research Opportunities and Needs of the NINCDS in the Neurological and Communicative Sciences," was conducted by a panel of 25 eminent scientists. I am happy to summarize it. The report began by identifying the new research methodologies now available to neuroscientists. Among the wide range of these powerful technologies are new brain imaging techniques such as positron emission tomography (PET) and nuclear magnetic resonance (NMR), techniques of molecular biology that permit observation of chemical processes in the nervous system, and techniques like the "patch clamp" that allow electrical recording of the functions of a single nerve cell. Other advances are the video-monitoring techniques used in epilepsy and in communicative disorders. The report also described with enthusiasm the many agonist and antagonist drugs for various neurotransmitters, neuromodulators, and neurohormones that will permit the development of more effective treatment of diseases such as Parkinson's disease and myasthenia gravis.

These methodological advances and what we have learned about the brain and nervous system to date open a new world of opportunities for neuroscience research. The panel concluded, "We have within our grasp the information, the tools, and the human resources to take the next significant steps toward understanding how the human brain works and to correct many of the disorders that affect it." The conceptual framework for understanding learning, thought, and behavior is now available. There are many specific opportunities in neuroscience today, as the panel observed. Among the areas requiring targeted and accelerated research efforts are developmental neurobiology, spinal cord and nervous system injury and degeneration, repair and regeneration, neuroimmunology, and neurogenetics. Opportunities also exist in the communicative sciences where, for example, research is needed in the complex functional brain disorders that impair reading and speech and in the pharmacological control of behavior. The panel determined that multidisciplinary centers, such as those the NINCDS now supports for PET, Huntington's disease, stroke, and other disorders, are particularly beneficial because they allow the pooling of talent and technologies in an atmosphere conducive to research. The panel noted that continued clinical trials and continued refinement of imaging techniques are critical to realizing these opportunities and that the fundamental information is now available to initiate these applied research activities.

Question. How much of what the report suggests can be accomplished within your budget for fiscal 1985?

Answer. I believe that the President's budget allows us to capitalize on several of the research opportunities identified by the independent scientists. For example, the panel called positron emission tomography (PET) and other imaging techniques "perhaps the most impressive and exciting of the new methodological approaches" in the neurosciences. NINCDS has been supporting an active intramural and extramural PET research program. Under the President's Budget we will have to limit the size and scope of these activities now underway but the program will be continued. The Institute is actively supporting and advancing pilot studies in many of the research areas which the Report describes. The issue is more one of intensity of support rather than breadth of support.

Question. What does the report say we must spend in fiscal 1985 and fiscal 1986 to keep pace with research opportunities? Are these amounts realistic?

Answer. The Panel of experts recommended $667.9 million for fiscal year 1985 and $986.4 million for fiscal year 1986. The Panel's recommendations assumed a higher level of funding for fiscal year 1984 than was actually appropriated. Consequently, the 1985 and 1986 recommended levels include continuation costs for projects that were not initiated in 1984. If adjustments are made for these differences, the actual 1985 figure would be $579.5 million.

## JAVITS AWARDS

Question. In its fiscal 1984 Labor-HHS bill, Congress specifically directed that $10 million of your appropriation be set aside for special scientific awards in honor of our former colleague, Senator Jacob Javits. I know, Doctor Goldstein, that you have spent a good deal of time on this project. And I was pleased to learn that one of the first awards has gone to Dr. Kent D. Morest of the University of Connecticut Health Center. Please bring us up to date on how this new program is progressing.

Answer. In 1984 the NINCDS will award research project grant support for a period of up to seven years to a select group of basic and clinical neuroscience and communicative science investigators who have a demonstrated history of scientific excellence and productivity, are actively pursuing an area of neuroscience or communicative research of strategic importance, and whose research proposal is of the highest scientific merit and offers high probability of continued accomplishment. This will account for the $10 million appropriated for the Javits awards for FY 1984.

In addition, upon the recommendation of a group of eminent outside advisors the NINCDS has proposed two other initiatives as Javits awards. The first is a program of Senator Javits Neuroscience Research Centers of Excellence which would provide stable research support to a select number of research teams to explore conceptual issues and to advance the cutting edge of neuroscience by focusing on the difficult long range questions. The second would be a program of Senator Jacob Javits Neuroscience Scholars. These would involve a limited number of career development applicants who would receive both stipends and research grant funds. The purpose would be to prepare young persons for careers as clinician-scientists to apply the concepts of the basic sciences to the problems of human pathology. Our Advisory Council has approved in principle the initiation of this program.

Question. How will your choice of award recipients relate to the study of research opportunities in the neurology field?

Answer. Those who have received the Javits Awards are a highly select group of outstanding basic and clinical investigators in the neurological and communicative sciences who have demonstrated their productivity and creativity in pursuing research of strategic scientific importance. The individual projects which they are conducting cover the broad range of the research opportunities in the neurological and communicative sciences described in the study.

Question. How much money do you plan to invest in the Javits scholarships in fiscal 1985 and beyond -- more than $10 million a year?

Answer. The $10 M awarded in FY 1984 to the Javits awardees will increase in fiscal 1985 and beyond through the seven year term of the awards by approximately 5 percent a year to take into account the annual increases in the cost of doing research.

Question. Does the fact that some of the awards will be for seven years break new ground in the biomedical research field -- or does it give other institutes a model to follow?

Answer. The seven year awards are intended to give stability of support to a select group of highly creative research investigators. The length of the awards does, indeed, break new ground towards achieving this stability. This could serve as a model for other Institutes.

## HUNTINGTON'S DISEASE MARKER

Question. One of the major developments of the past year was the announcement that researchers have discovered the genetic marker for Huntington's Disease. What is the significance of this finding both for screening possible victims and for treating the disease?

Answer. One potential value of such a marker is the ability to predict the likelihood of occurrence of disease in people at risk for the illness who may have inherited the gene from an affected parent but do not express the illness until middle life. Such tests are now being done on a pilot basis on selected individuals with families who have well-documented genetic histories of Huntington's Disease. As for treatment, by using modern techniques in genetic research, it may someday be possible to correct the genetic defect.

Question. When could such tests for Huntington's begin?

Answer. With the present state of the art such predictive testing would only be useful in about half of the individuals at risk and would be subject to an unacceptable degree of uncertainty. To improve the utility of the test will require extensive validation and reduction in sources of error. A more promising prospect lies in further refinement of the molecular genetic research now going on to move from the adjacent genetic marker to the critical gene itself which would then be far more informative for prediction of the disease. This research effort is continuing but is expected to take several more years. The achievements to date indicate that we can have a high degree of confidence about the feasibility of reaching this goal.

Question. Could there be both pre-natal and post-natal tests for the disease?

Answer. Yes, a wholly satisfactory genetic diagnostic test could quite likely be applied both to persons at risk for development of the disease and be applied as a pre-natal test. But, again, much work remains before practical tests will be available.

Question. To what extent can the techniques that led to discovery of the marker for Huntington's be used to test for other genetic disorders?

Answer. The application of the techniques of modern molecular genetics to several of the hereditary diseases of the nervous system is a very active area of current research. As we learn more about using recombinant DNA techniques to map the human genome, we will find it applicable to understanding numerous neurological diseases which have a genetic basis or component. Some important examples are neurofibromatosis, Gaucher's disease, tuberous sclerosis, the muscular dystrophies, and perhaps Alzheimer's disease and epilepsy.

Question. What role, if any, did NIH play in the discovery of the Huntington's Marker?

Answer. The National Institute of Neurological and Communicative Disorders and Stroke and the National Institute of General Medical Sciences jointly supported the work of the research teams which discovered the marker. In addition, the NINCDS staff led a series of expeditions to the Lake Maracaibo region of Venezuela where there is a large cluster of Huntington's Disease patients. These expeditions collected tissue samples from patients and relatives and developed and validated an extensive pedigree showing the relationships among the victims and their families. The samples and the pedigree were indispensible tools for this research.

Question. How much are you spending on research into this disease?

Answer. The budget estimate for research specifically on Huntington's disease (HD) is $2,900,000 in 1984 and $3,000,000 in 1985. For total HD and HD related research, the estimate is $14,800,000 in 1984 and $15,200,000 in 1985.

## ALZHEIMER'S DISEASE

Your Institute, together with others at NIH, supports research on Alzheimer's Disease.

In view of the importance of this research, and the priority Congress places on it, why are you projecting only a $306,000 increase in your research funding for this area in FY 85?

| | |
|---|---|
| FY 84 appropriation | $10,924,000 |
| FY 85 request | 11,230,000 |

Answer. The President's Budget for 1985 has a 2.8 percent increase over 1984 for NINCDS. The increase for Alzheimer's

Disease is approximately 2.8 percent which is consistent with the overall budget estimate.

Question. What advances have you made against this disease in the past year?

Answer. An NINCDS grantee has shown that in Alzheimer's disease, there is a selective death of certain specific nerve cells in the basal forebrain which utilize the neurotransmitter, acetylcholine. Other research had implicated acetylcholine as an important neurotransmitter in memory. Investigators are working intensely to describe and understand the connections between the basal part of the brain and the outer mantle where higher mental functions are carried on. Deficiencies of other chemicals used as neurotransmitters such as somatostatin and noradrenalin have also been demonstrated in the brains of Alzheimer's disease patients. New methods have been developed to describe the organization and the topography of the connections which make up the "thinking" brain. Recently, PET studies of patients with Alzheimer's disease showed focal decreases in brain glucose metabolism, especially in the temporal and parietal brain lobes. Other important research findings relate to new observations about the chemical properties of neurofibrillary tangles and of senile plaques, the two pathological hallmarks of the disease in the brain. Intriguing leads from the study of degenerative brain diseases such as scrapie, in animals, provide clues to the possible origin of the amyloid component of the senile plaque. Thus a number of exciting leads as to both the possible cause and the pathogeneses of Alzheimer's disease have been documented.

Question. And what are your areas of research emphasis in the new fiscal year?

Answer. Extension of this research will be emphasized in the coming year with a variety of studies which include detailed chemical analyses of the affected nerve systems, attempts to study these systems in aged primate models, and studies in humans which correlate dementia symptoms with localized metabolic changes in the brain as revealed by Positron Emission Tomography (PET.) Other studies will focus on slow virus infection of the nervous system utilizing animal slow virus diseases which may serve as models of how slow viruses can cause chronic degenerative neurological disorders.

Question. Which research avenues would you pursue if you were not constrained by budget limitations?

Answer. The most promising areas of research relevant to Alzheimer's disease which would benefit from expanded funding are: anatomical, physiological, chemical, and behavioral studies of the normal and damaged nervous system in humans and experimental animals, and of neurotransmitter systems specifically affected by the degenerative disorder; extended Positron Emission Tomography (PET) studies of brain metabolism, and nuclear magnetic resonance (NMR) studies of brain structure, to define more precisely the brain substrate of obvious dementia, correlating the imaging findings with symptoms and the clinical course of the illness; modeling studies of behavior, memory, and cognitive deficits in experimental animals which can be subjected to surgical lesions and pharmacological manipulations of brain systems implicated in Alzheimer's disease; genetic and epidemiological studies designed to define and elucidate the contribution of heredity and other risk factors to the basis of Alzheimer's disease; and longitudinal prospective clinical studies of aging human populations to improve diagnostic criteria and to identify risk factors for prediction and prevention.

## SPINAL CORD RESEARCH

Question. The study of neurological research opportunities makes this statement: "In the brain and spinal cord, damage and degeneration characterize the largest and most devasting group of neurological disorders, yet the opportunities for major advances in understanding and treating them have never been better." One area of continuing interest to the Subcommittee has been in spinal cord damage and regeneration. What are we now capable of accomplishing in this field?

Answer: Considerable progress has been made toward understanding the basic mechanisms that occur early after spinal cord injury. Certain biochemical events appear to add to the already existing damage. Current studies are defining these specific biochemical events and the mechanisms by which their effect may be reduced. Other investigators have developed research methods to bridge damaged spinal cord with specific nerve segments. Growth of axons bridging the damaged area can be demonstrated; however, the means by which functional connection of these bridges takes place remain elusive. Intensive efforts are being directed toward defining these specific problems and finding ways of managing them.

Question. It appears you spent about $19 million in fiscal 1983 on spinal cord injury and nervous system regeneration, and you estimate that $21 million will be spent in this area during the current fiscal year. To what extent are these levels of funding sufficient to deal with the research opportunities now available in the field?

Answer. There are a number of additional research opportunities in this area. The 1985 funding plan for spinal injury and regeneration will maintain the 1984 level of effort. This is consistent with the funding plans for other disorders within the responsibility of the Institute.

## MULTIPLE SCLEROSIS

Question. Your special study on Multiple Sclerosis -- MS -- states that "no safe and effective treatment for MS yet exists."

What clinical trials do you have underway that may lead to some advances against this disease?

Answer. Current clinical trials on multiple sclerosis include: a study of azathioprine and steroids in the treatment of multiple sclerosis; study of plasmapheresis in the treatment of acute multiple sclerosis; clinical trial of Copolymer I treatment of ER (Exacerbating-Remitting) multiple sclerosis; clinical trial of Copolymer I treatment of C-P (Chronic-Progressive) multiple sclerosis; multicentered clinical trial of thymosin in multiple sclerosis through immune modification in controlling the frequency of attacks and severity of progression of disability of multiple sclerosis; and intrathecal interferon treatment of multiple sclerosis.

Question. What progress do you hope to make through intramural research?

Answer. Although the successful treatment of multiple sclerosis remains elusive, therapeutic trials in disease continue to be conducted in the NINCDS intramural research program. Over the past year, a study of lymphocyte depletion was completed and found not to halt rapidly progressive MS. Currently, two new approaches are in progress. First, there is a study on the transfer of normal lymphocytes into an affected identical twin. Secondly, a trial of Poly ICLC, an interferon inducer and immunomodulator, is being conducted in patients with progressive multiple sclerosis. During the forthcoming year, it is anticipated that a Phase III trial of Cyclosporin A, an immunosuppressant, will be initiated using a double blind protocol.

Question. We understand that a substance known as "myelin" may play a role in the development of MS. What can you tell us about your efforts to elucidate such a possible role?

Answer. Myelin is the layered fatty material which surrounds nerve fibers in both the central nervous system (brain and spinal cord) and in peripheral nerves. It may be compared to the insulation around an electric wire. It is produced during development by specialized cells of the nervous system and its maintenance is essential to normal nerve impulse transmission. In multiple sclerosis, for reasons that are still poorly understood, myelin is destroyed by a mysterious reaction, probably of a so-called auto-immune type; this results in nerve fibers becoming demyelinated and failing to conduct nerve impulses normally. This disturbance of nervous transmission is the basis of the varied and manifold symptoms of multiple sclerosis ranging from loss of vision to loss of motor function.

In view of this central feature of myelin loss, or demyelination, as the essential pathological basis of multiple sclerosis, it is not surprising that much of our very active and productive research in this disease area focuses on myelin. We support extensive studies of the chemistry of this complex substance, on its microscopic structure, and on its ability to trigger an immune response, as well as a wide range of studies of its degeneration in related neuroimmunological disorders and inflammatory conditions. All of these studies are directed at clarifying why and how myelin is damaged in multiple sclerosis, and whether and how this damage can be prevented or reversed.

Question. Last year's committee report placed a great deal of emphasis on Multiple Sclerosis and other degenerative disorders. Where have we been and where are we going in terms of dollar commitments to this high priority area?

Answer: In fiscal year 1983, the NINCDS supported a total of $31,080,000 for multiple sclerosis and multiple sclerosis related research. The 1984 estimate is $35,100,000 and the 1985 President's Budget estimate is $36,080,000.

Question. Are there any clinical trials in this area which are ready to be funded?

Answer. If additional funds were available, we would initiate a multicentered clinical trial to evaluate the use of Copolymer I to eliminate exacerbations in patients with ER (exacerbating-remitting) multiple sclerosis. We are also evaluating one other method of intervention but have not yet come to a final conclusion about the scientific importance of a trial at this time.

## AUTISM

Question. We are aware of the fact that you have organized a section on autism and behavioral disorders in an effort to find the cause and cure of autism. What progress are you making in your research into this disorder of early childhood?

Answer. In September, 1983 a Workshop on Research Definitions of Autism and Related Disorders brought together a dozen nationally prominent experts to lay the foundation for studies of comparable autistic patients so that neurobiological findings can be replicated or refuted reliably.

The NINCDS will use the results of this workshop for further program development. In addition, two research projects concerning electrophysiology (electrical activity of the brain) in autism were funded and began work in September 1983.

Question. What are the most promising lines of research that you are following, and are they adequately funded?

Answer. The areas of research showing most promise at present are: electrophysiology (electrical activity of the brain; precise measurement of clinical signs; neurobiochemical investigation; and post-mortem brain studies. The budget request for 1985 will permit the NINCDS to maintain the level of effort achieved in 1984.

## TECHNOLOGICAL DEVELOPMENTS

Question. The Subcommittee has followed the technological revolution that has led to such significant techniques as CAT and PET scans and Nuclear Magnetic Resonance (NMR). To what degree do these technological tools overlap in their function or usefulness and which is the safer of the three?

Answer. While CT, NMR, and PET are all brain imaging devices, they produce quite different but complementary information. CT scanning, in general, shows the anatomical structure of the brain, PET shows its metabolic activity. NMR, like CT, shows anatomical structure; it can also indicate cerebral biochemical alterations, particularly those involving water, fats, and proteins. Comparing a PET scan with a CT scan, for example, allows the investigator to examine metabolic activity in the brain and correlate it with alterations in specific anatomic areas. Thus, patients with a wide variety of diseases such as stroke, Huntington's disease, brain tumor, Parkinson's disease, and epilepsy can be examined and the anatomic location of specific metabolic errors identified.

The PET scan remains a research tool for unraveling biochemical concerning clinical disease and the ways in which that disease may be modified. While a PET scanner is located a in patient research settings, it is not a standard diagnostic tool but a research instrument. The equipment requires both the use of radioisotopic drugs and highly complex analytic methodology. The information learned from PET scans of carefully selected patients are helping us unravel biochemical abnormalities that may be present and therefore permit us to understand the disease process better. NMR scanners are commercially available and are currently being installed for clinical use in hospitals. While NMR produces excellent images, it is too early to determine the impact it ultimately may have on neuro-diagnostic procedures. NMR has an important advantage in that it does not expose patients to ionizing radiation. It requires extremely powerful magnets with carefully designed shielding and enclosures.

The promise of these noninvasive technologies is especially important for study of the brain and its disorders, which has for enturies been inaccessible to study. All three technologies are safe and important.

Question. How does ultrasound fit into the picture?

Answer. Ultrasound is a methodology by which the flow characteristics of blood in a vessel can be examined and to a certain degree quantified. The technique is useful for determining blood flow in large vessels outside the brain such as the carotid artery in the neck. It shows, with a fair degree of precision, qualitative aspects of blood flow and provides partial images of pathology. On the other hand, CT scanning is utilized for demonstrating specific anatomic changes within the brain and brain substance. Dynamic CT scanning can also demonstrate certain aspects of blood flow. PET scanning reveals metabolic activity within normal and diseased brain and can quantify blood flow in normal and damaged parts of the brain; it can also indicate the consumption of oxygen and glucose in these areas. The medical use of NMR is too early in its application to be fully evaluated; however, it appears promising. It is unlikely that ultrasound will replace any of the scanning modalities because they address different, but often complementary, issues.

Question. Will it edge out any of the other techniques for research on such diseases as Alzheimer's, multiple sclerosis, etc.?

Answer. Ultrasound has not been demonstrated to be useful in the diagnosis of Alzheimer's disease or multiple sclerosis.

Question. What roles have NMR and PET played in research into trauma of the head and spinal cord.

Answer. Because of the severity of injury in patients with head injury, it continues to be difficult to apply PET scanning methodology except under the most carefully controlled circumstances; however, several investigators are determining some of the metabolic derangement that takes place in patients with head injury in order to improve our understanding of these deficits and apply appropriate treatment. Imaging of the spinal cord is currently being utilized with high-resolution scanning equipment, which is in its early stages of evaluation but which appears very promising. Although it is too early to evaluate the use of NMR in research on trauma of the head and spinal cord, it is a noninvasive technique. For example, NMR permits the detection of soft-tissue lesions at anatomical sites where soft tissue adjoins hard tissue such as bone. Consequently, scientists have been able to detect certain lesions on the spinal cord, such as neural tumors and intervertebral disk abnormalities, not seen by CT scanning. Thus, it is important to recognize that NMR is not just an improved technique; it is a different technique that will complement other imaging techniques rather than replace them. By contrast, CT scanning is used extensively for the determination of anatomic disruption of the brain secondary to trauma. It can show with considerable precision the presence of a blood clot and the extent to which the brain has been subjected to damage. It is an excellent modality for monitoring patients post-operatively.

Question. You have described PET and the other new imaging technologies in the past, Doctor. What would you say is the promise of these technologies?

Answer. The ability to watch the human brain at work in the living person which PET technology provides is moving into an extraordinarily sophisticated and exciting period. While the last several years have been devoted to the installation and calibration of this complex equipment and the evaluation of normal physiology, research is now more and more directed toward defining metabolic abnormalities in a wide variety of diseases. The actual decrease in brain oxygen consumption or glucose utilization can be assessed in patients who have suffered a stroke. Areas can be defined where the brain has potential for recovery. An improved understanding of brain biochemistry, brain blood flow, causes of stroke, hydrodynamics, and the response of the brain to injury holds promise for therapy that may prevent the stroke entirely or lessen its severity and progression. The sequence of events related to epileptic seizures and their correlation with brain pathology are now being studied. A better understanding of these patterns should allow more rational design of treatments. Also exciting is the development of highly specific compounds that permit detection of important receptor sites used for transmission of information in the brain. These sites are lost or altered in some diseases. PET allows investigators in movement disorders such as Parkinson's or Huntington's diseases to look at such receptor changes. Brain tumors show remarkable variations in their metabolic activity. Investigators are studying the significance of this variability and how treatment such as x-ray or chemotherapy changes the response of the cancer.

The ability to look at the structure of the brain in the living person has been greatly enhanced by the development, initially, of CT scanning and more recently, by nuclear magnetic resonance (NMR) imaging. While still under development, NMR promises to be very useful for looking at specific parts of the brain where the bones of the skull make CT scans less precise. Scientists are also developing another type of NMR which will allow us to look at energy utilization in the brain without any need for radioactive materials.

The promise of these new noninvasive technologies is especially important for study of the brain and its disorders, which has for centuries been inaccessible to study.

What are the resources that will be required to continue your Institutes's PET program?

Answer. Five years agc, the Congress provided the Institute with funds to establish the PET research program. All of these grants were awarded at essentially the same time and they are now up for competitive renewal. Most of them are in the review process and we estimate approximately $10 million would be needed to fund all approved PET grants. However, we estimate the funding rate for competing research grants in 1985 to be 29 percent of approved grants. This being so, the funding of the $10 M of approved PET grants which fall within the priority score funding level will be approximately $3 million in FY 1985.

## CLINICAL TRIALS

Question. In the fiscal 1984 report, the Committee asked you about your work on clinical trials which is a way to move research to a conclusive outcome.

The Subcommittee notes that in fiscal 1983 you funded 49 clinical trials at a cost of $8.1 million. How much will you spend on trials in fiscal 1984 and fiscal 1985?

Answer. The budget estimate for clinical trials is $9,322,000 in 1984 and $9,650,000 in 1985.

Question. What areas will your trials focus on?

Answer. Clinical trials will include the areas of stroke, head and spinal cord injury, multiple sclerosis, Guillain Barre Syndrome, epilepsy, Reye's Syndrome, otitis media, febrile seizures, neurological complications of diabetes, Tourette's Syndrome, Parkinson's disease and the movement disorders, intracranial hemorrhages, coma, and brain tumors.

## EPILEPSY RESEARCH

Question. Your budget increased substantially between 1978 and 1983, yet we're told funding for epilepsy research increased by a mere $2.5 million. What can you do to stimulate more research on epilepsy?

Answer. In FY 85, the Institute is proposing several new initiatives to promote epilepsy research. One initiative is support of research to improve prevention and treatment of neonatal seizures through more accurate methodology for recognition and classification of seizures. Other initiatives include studies to determine why antiepileptic drugs become less effective with time, and what factors are responsible for prolonged seizures. We will encourage investigators to apply the powerful new technologies of cell biology to elucidate the basic causes of epilepsy.

Question. Last year, this Subcommittee heard much about the Epilepsy Branch and its five-year national study aimed at preventing injury-caused epilepsy. Could you please give us a progress report on this study.

Answer. The Institute is currently supporting a study to evaluate the efficacy of antiepileptic drugs in preventing epilepsy following head injury. Results from this study, which has recently started, will be available in 1988. The Institute anticipates additional grant applications in this important area.

Question. You apparently were evaluating the efficacy of several new drugs under the Antiepileptic Drug Development program. What has happened to these evaluations?

Answer. Currently, we are conducting 5 clinical trials on new drugs for treatment of epilepsy. These substances are promising candidates for becoming a regular part of epileptic treatments avaiable to physicians.

Question. And what new developments do you anticipate this year?

Answer. There are a number of new substances which are undergoing tests for toxicology in animals. Several of these will become candidates for clinical trials.

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## Questions Submitted by Senator Mark Andrews

### RESEARCH OPPORTUNITIES AND NEEDS

Question. Last year, this subcommittee arranged for an independent study of research opportunities in the neurosciences. What were the results of this study?

Answer. The independent study of research opportunities in the neurological and communicative sciences was conducted by a panel of 25 eminent scientists. The resulting report, entitled, "An Evaluation of Research Opportunities and Needs of the NINCDS in the Neurological and Communicative Sciences," was submitted to you and your Committee and I am happy to summarize it. The report began by identifying new methodologies available to neuroscientists for the first time. Among the wide range of powerful technologies are new imaging techniques such as positron emission tomography (PET) and nuclear magnetic resonance (NMR), molecular biology techniques that permit observation of chemical processes in the nervous system, and techniques like the "patch clamp" that allow electrical recording of the functions of a single nerve cell. Other advances are the video-monitoring techniques used in epilepsy and in communicative disorders. The report also commented favorably about the many agonist and antagonist drugs for various neurotransmitters, neuromodulators, and neurohormones that allow more effective treatment of diseases such as Parkinson's and myasthenia gravis.

Question. What major opportunities are before us?

Answer. These methodological advances and what we have learned about the brain and nervous system to date open a new world of opportunities for neuroscience research. The panel concluded, "We have within our grasp the information, the tools, and the human resources to take the next significant steps toward understanding how the human brain works and to correct many of the disorders that affect it." The conceptual framework for understanding learning, thought, and behavior is now available. There are many specific opportunities in neuroscience today, as the panel observed. Among the areas requiring targeted and accelerated research efforts are developmental neurobiology, spinal cord and nervous system injury and degeneration, repair and regeneration, neuroimmunology, and neurogenetics. Opportunities also exist in the communicative sciences where, for example, research is needed in the complex functional brain disorders that impair reading and speech and in the pharmacological control of behavior. The panel determined that multidisciplinary centers, such as those the NINCDS now supports for PET, Huntington's disease, stroke, and other disorders, are particularly beneficial because they allow the pooling of talent and technologies in an atmosphere conducive to research. The panel noted that continued clinical trials and continued refinement of imaging techniques are critical to realizing these opportunities and that the fundamental information is now available to initiate these applied research activities.

Question. What resources did the study identify as necessary to capitalize on these opportunities?

Answer. The Panel of Consultants recommended $667.9 million for fiscal year 1985 and $986.4 million for fiscal year 1986.

Question. It does not appear that the Administration's budget request adopts the recommendations of this report. Would you please elaborate?

Answer. The independent evaluation report documents the exciting and inspiring new research opportunities in the neurosciences and communicative sciences. The recommendation of the scientific panel that prepared the report was $667.9 million for 1985 compared to the 1985 President's Budget request of $344.6 million. However, the panel's recommendations assumed a higher level of funding for fiscal year 1984 than was actually appropriated. Consequently, the 1985 and 1986 recommended levels include continuation costs for projects that were not initiated in 1984. If adjustments are made for these differences, the actual 1985 figure would be $579.5 million.

## ALZHEIMER'S DISEASE

Question. NINCDS and other institutes support research on Alzheimer's Disease. What are the areas of NINCDS research emphasis?

Answer. Alzheimer's disease is a disease of the brain. The NINCDS-supported research efforts concentrate on developing new knowledge of the neurobiological bases, both structural and metabolic, for the development of Alzheimer's disease in the expectation that the knowledge generated will provide opportunities for treatment and prevention. We support research on risk factors, etiology and pathogenesis, diagnosis, possible therapeutic approaches, and on prevention.

Question. What advances have been made by your Institute during this past year?

Answer. Some important areas of intensive research activity at the present time focus on the role of localized brain degeneration in groups of nerve cells (basal nuclei) deep in the brain which selectively degenerate in Alzheimer's disease. Scientists have found that these neurons project to the cerebral cortex with connections critically dependent upon the important neurotransmitter, acetylcholine. The degeneration of these cholinergic cells and their connections seems to play a central role in the development of Alzheimer's disease.

Question. Which research avenues would you pursue if you were not constrained by budget limitations?

Answer. The most promising areas of research relevant to Alzheimer's disease which would benefit from expanded funding are: anatomical, physiological, chemical, and behavioral studies of the normal and damaged nervous system in humans and experimental animals, and of neurotransmitter systems specifically affected by the degenerative disorder; extended Positron Emission Tomography (PET) studies of brain metabolism, and nuclear magnetic resonance (NMR) studies of brain structure, to define more precisely the brain substrate of dementia, correlating the imaging findings with the symptoms and clinical course of the illness; modeling studies of behavior, memory, and cognitive deficits in experimental animals which can be subjected to surgical lesions and pharmacological manipulations of brain systems implicated in Alzheimer's disease; genetic and epidemiological studies designed to define and elucidate the contribution of heredity and other risk factors to the basis of Alzheimer's disease; and longitudinal prospective clinical studies of aging human populations to improve diagnostic criteria and to identify risk factors for prediction and prevention.

## EPILEPSY

Question. The NINCDS budget increased $120 million between 1978-1983. However, funding for epilepsy research only increased by $2.5 million. Epilepsy research funding as a percent of the NINCDS total declined from 9.1-6.5 percent. What can NINCDS do to stimulate further research on epilepsy?

Answer. In FY 85, the Institute is proposing several new initiatives to promote Epilepsy research. One initiative is support of research to improve prevention and treatment of neonatal seizures through more accurate methodology for recognition and classification of seizures. Other initiatives include studies to determine why antiepileptic drugs become less effective with time, and what factors are responsible for prolonged seizures. We will encourage investigators to apply the powerful new technologies of cell biology to elucidate the basic causes of epilepsy.

Question. This committee has supported the Antiepileptic Drug Development program over the years. Last year we were informed that the program was evaluating the efficacy of several new drugs. What has happened to these studies?

Answer. Currently, we are conducting 5 clinical trials on new drugs for treatment of epilepsy. These substances are promising candidates for becoming a regular part of epileptic treatments avaiable to physicians.

Question. And what new developments do you anticipate this year?

Answer. There are a number of new substances which are undergoing tests for toxicology in animals. Several of these will become candidates for clinical trials. Overall, the Institute plans to initiate clinical trials on two new substances each year for the next several years.

## STROKE

Question. As our population continues to age, we will witness more cerebal vascular disease, not less. I firmly believe that this will warrant additional clinical research into this crippling disease. In the past, we have funded 18 active stroke clinical research centers. Last year, there were 12 active centers. Is it your belief that additional centers are needed? And if so, how many?

Answer. At the request of the House Committee on Appropriations, the NINCDS submitted a report in February, 1984 on Cerebrovascular Clinical Research Centers. In that report the Institute expressed a belief that with the advent of today's technology including Positron Emission Tomography and Nuclear Magnetic Resonance combined with recent advances in our basic understanding of the brain and the central nervous system, the opportunity existed for additional stroke research centers which could prove very fruitful in advancing knowledge of the processes and treatment of stroke. We believe that 12 additional stroke research centers could be developed if this single program is viewed in the absence of competing priorities and opportunities in other areas of neurological research.

Question. Should one aspect of the Stroke Center be devoted to the development of a public education program?

Answer. Although the major thrust of the proposed Stroke research centers will be to improve prevention through earlier identification of risk fctors, a well-designed center might well include efforts to improve public dissemination of such advances.

## BACK PAIN

Question. Back pain has been a burden to mankind since creation. It is one of the causes of absenteeism from work. Is NINCDS presently devoting any research to back pain?

Answer. Back pain is a serious and ubiquitous problem. The NINCDS receives few applications related to back pain because it is a diffuse and poorly defined symptom for which quantitative measurement is difficult to achieve. Nevertheless, investigators have been and are being encouraged to develop appropriate research proposals to address this important question.

Question. If not, do you believe that clinical research in this area could take place with the development of a Center for the Study of Back Pain?

Answer. Research centers devoted to back pain would be valuable particularly as they would focus attention on a serious and important disease process. In addition, inherent in the design of a center would be the opportunity for the investigators to address significant and important clinical research questions, as well as the methods by which they would be able to perform this research, and the probability of a successful outcome from such research. Projects related to evaluation of back pain are currently being developed for submission to the NINCDS.

Question. Do you have an estimate as to the cost to start up funds for such a center?

Answer. Estimated start-up cost for the fiscal year would be about $500,000 per center.

## Questions Submitted by Senator William Proxmire

### EPILEPSY

Question. Dr. Goldstein, can you tell us how much your Institute plans to spend on epilepsy next year?

Answer. The 1985 President's budget estimate for epilepsy is $22,560,000.

Question. On August 29 of last year the Institute awarded approximately $250,000 in direct costs for a three year study to determine the prevalence of epilepsy in children from birth to age 19 in two counties in Oklahoma. How will the results of this study be utilized?

Answer. The results of this study are expected to provide clues to the causes, prevention, and treatment of seizures in this age group.

### PROJECT CONTRACTS

Question. Dr. Goldstein, although the Congress increased your budget in fiscal year 1984, I notice that you plan to cut the amount spent on project contracts from the $16,023,000 included in last year's submission to a revised figure of $15,206,000. Can you tell us why?

Answer. Within the fiscal constraints for development of the 1984 President's Revised Budget, the highest priority is being given to the support of new and competing grants, research training and maintenance of the 1984 number of clinical research centers. To assure the availability of core funds for these high priority items, funds available for research contracts were reduced.

## SPINA BIFIDA

Question. Dr. James O. Mason, Director of the Center for Disease Control, reports that its studies and surveillance of birth defects have uncovered convincing evidence of the association between the use of the anticonvulsant drug valproic acid during pregnancy and the occurrence of spina bifida. Can you tell us what impact this finding has had on the Institute's research?

Answer. The occurrence of teratogenic effects from valproic acid, such as spina bifida has been difficult to predict. The Institute is funding research to determine if an animal model can be used to help predict teratogenic effects. The model will first be applied to already marketed antiepileptic drugs and if it proves useful, it will then be used in studies to assess the teratogenicity of new antiepileptic drugs before they are available to the public.

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## QUESTION SUBMITTED BY SENATOR QUENTIN N. BURDICK

Question. I understand that while the budget for NINCDS increases by 67% from 1978 to 1983, money for research on epilepsy increased only 19%. During those years, epilepsy research has become a smaller portion of the NINCDS budget, overall. Could you please explain why this decline has taken place and if any efforts are underway to reverse it?

Answer. In 1976 the Institute initiated, under contract, five comprehensive epilepsy centers to mobilize community resources and enhance community outreach activities to aid in the treatment of epilepsy and to enhance clinical research activities. These projects were limited to five years of research contract support after which these centers competed in the usual grant application and peer review process. Two of the five centers competed successfully as grants, the others being approved while receiving research merit priority scores which were too low to permit funding.

In order to reverse the apparent decline in epilepsy research, in FY 85, the Institute is proposing several new initiatives. One initiative is support of research to improve prevention and treatment of neonatal seizures through more accurate methodology for recognition and classification of seizures. Other initiatives include studies to determine why antiepileptic drugs become less effective with time, and what factors are responsible for prolonged seizures. We will encourage investigators to apply the powerful new technologies of cell biology to elucidate the basic causes of epilepsy.

## NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

## STATEMENT OF DR. RICHARD M. KRAUSE, DIRECTOR

**ACCOMPANIED BY:**

- **DR. BERNARD TALBOT, DEPUTY DIRECTOR**
- **DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. We will hear next from the National Institute of Allergy and Infectious Diseases which has a major role in the current battle to find the cause and treatment required for the acquired immune deficiency syndrome.

The budget request for the Institute is $325 million or about $11 million more than the appropriation for fiscal year 1984. Here to testify is our good friend, Dr. Richard Krause. He's the Director.

Staff tells me you're going to be moving on to new challenges. I want to hear about that, but why don't you go ahead and present yourself and your colleagues, Doctor.

Dr. KRAUSE. It's good to meet with you again, Mr. Chairman. After hearing some of the questions from the Senate side during the course of the morning, I have completely altered my brief opening remarks.

[The statement follows:]

## STATEMENT OF DR. RICHARD M. KRAUSE

Modern medicine began with Pasteur. He was the most prominent among those who established the germ theory of disease. That was barely 100 years ago. What a novel idea that was--the notion that microbes, invisible to the naked eye, could cause disease, suffering and death! We accept that now. We take for granted the vaccines and antibiotics that have flowed from Pasteur's vision. And yes, the public health measures such as the chlorination of water and the pasteurization of milk. Pasteur's legacy overthrew an archaic style of medical practice that dated back to ancient Greek medicine. A tradition of 2000 years overturned within one century.

The significance of Pasteur's discovery does not end with the identification of microbes as the cause of disease and the development of vaccines and antibiotics. Research on microbes has led to new knowledge about many different aspects of health and noninfectious diseases--knowledge never anticipated in the remarkable mind of Pasteur. Microbes, we are learning, can play a role in many chronic diseases such as some forms of arthritis and neurologic diseases. Infections are linked to the development of immunologic disorders. And who would have imagined that microbes would have played the leading role in the development of genetic engineering?

Let me start at the beginning. One hundred years ago the search began--like a mad gold rush--to discover a microbial cause of each and every disease. Identified beyond question were the causes of tuberculosis, pneumonia, typhoid, meningitis, cholera, influenza, polio, rubella and measles. Many of the most serious infections were successfully treated with antibiotics--wonder drugs to those who remember the epidemics of the past. Others, such as polio and rubella, were prevented with vaccines.

Because of these successes, the medical profession and the public dismissed infections as a serious threat to health. Other factors abetted this complacency. There was a growing belief that many illnesses were due to causes other than microbes. There was no obvious evidence implicating infections as the cause of chronic diseases such as arthritis, diabetes, multiple sclerosis, arteriosclerotic heart disease, endocrine disorders, or cancer. Metabolic and genetic defects were proposed as the cause of their development. Medical research moved briskly into these avenues while research on infections declined.

But we were wrong in our assessment that infectious diseases had been conquered, and we were wrong for several reasons. We thought that with antibiotics we had secured a tight noose on the microbial world, only to find bacteria had wriggled through the antibiotic barrier by developing resistance. Gonorrhea is epidemic today. This is due, in part, to the fact that it takes 40 times as much penicillin to treat these patients today as it did at the end of World War II. Indeed, certain gonorrhea organisms are so resistant that penicillin is completely ineffective. Other bacteria persist as deadly pathogens despite the use of antibiotics. Pseudomonas in cystic fibrosis patients is one such example.

Despite the campaign against some of the most ferocious infectious diseases, there remain at least 200 known infections that rage out of control. It is a fact that at least one in every five patients who seeks medical care does so for an infection. In most instances these are due to viruses for which we have neither the means of treatment nor prevention.

Now we are returning to the notion that some chronic diseases are linked to an infectious process. Last year I described to this Committee the discovery of the microbe that causes Lyme disease, a chronic illness of the joints, heart, and brain, common in the northern tier of states. Early detection and treatment of this infection are essential to prevent the chronic complications. We are searching for possible infectious causes of other chronic diseases such as multiple sclerosis, diabetes, the dementias, and arthritis. We are examining a wide variety of animal viral infections, hoping to unravel the ways that infections can produce such chronic diseases and then develop methods of treatment and prevention.

Infections are also suspected of playing a role in immune-related diseases. Just as microbes may cause chronic diseases by a direct attack on vital organs, it is possible that microbes provoke destructive immune processes. The current epidemic of Acquired Immune Deficiency Syndrome (AIDS) is one dramatic example of this. NIAID is conducting research to identify the agent(s) causing AIDS, and to define the epidemiology and natural history of the disease. Investigations are underway to detect the disease early, to determine immunologic abnormalities in AIDS patients, and to develop therapy to reconstitute the failed immune system. The NIAID is also conducting research on the life-threatening infections that kill AIDS patients, and developing new drugs to treat these infections.

AIDS research is producing significant spin-offs. In addition to penetrating the AIDS mystery, we are learning about the complex relationship between infections and the immune system, a relationship that may be important in the development of chronic disease. From the devastation that is AIDS will come, I am certain, answers to some very key questions about human health and diseases such as immune deficiency and cancer.

Not so many decades ago scientists had little understanding of the immune system. Physicians had observed, since antiquity, that many infections such as measles and other childhood diseases stimulate lifelong immunity to reinfection. And once it was understood that microbes were responsible for both infection and immunity, it was only a matter of time before scientists developed vaccinations to reproduce this immunity. But exactly how this remarkable protection came about remained a mystery. It was a mystery in 1796 when Jenner introduced vaccination for smallpox; it was still a mystery when Jonas Salk and Albert Sabin introduced the polio vaccines of the 1950s.

But this is rapidly changing. Scientists are now learning the roles played by each component of the complex network of organs and cells that make up the immune system. We are learning, too, how this extraordinary system may cause disease. Deleterious immune processes are responsible for common allergies, such as asthma and hay fever. Important advances have been made in improving the efficacy of allergy shots. And new ways are being explored to prevent asthmatic attacks from reaching the stage that results in absenteeism from work and school.

A malfunctioning immune system is responsible for a large number of the autoimmune diseases; systemic lupus erythematosus is one example. Some of the immunological abnormalities in lupus are now known. For example, special blood components, called complement, amplify the powers of the immune system; these are frequently absent in lupus patients. This unexpected finding will lead into new lines of investigation on how immune processes damage vital organs in lupus patients. Such research will in turn redirect efforts to new forms of therapy.

AIDS has focused widespread attention on immune deficiency diseases. These diseases occur when one or more parts of the immune system are missing or do not function properly, subjecting the body to unrepelled invasion by ordinarily harmless microbes. There is also growing evidence that the immune system is linked to the development of many chronic diseases such as rheumatoid arthritis, multiple sclerosis, and some forms of cancer.

Because of recent technical breakthroughs there are new opportunities to expose the internal complexities of the immune system. One major advance is the discovery of the "hormone-like" signals, called interleukins, that regulate the immune system. One interleukin stimulates the immune system to increase the immune barrier; another interleukin suppresses the activity of the immune system. In the normal person a healthy balance is achieved between these two opposing forces. It is anticipated that many more hormones will be discovered, each elaborating and modulating the two opposing forces until the complex mechanisms of immunity are clearly defined. Already, practical benefits have come from this basic work. Clinical trials are now underway to use interleukin in the treatment of patients with immune disorders.

Nowhere is the relationship between the immune system and infections more apparent than in the process of immunization. Here I have good news. Immunization remains the primary method of disease prevention; it stimulates the ever-vigilant immune system against the threat of infection. Revolutionary new tools, such as recombinant DNA and monoclonal antibodies, will permit us to develop vaccines years faster than we could using traditional methods. Vaccines for at least 30 different bacterial, viral, and parasitic diseases are in the developmental stage. Those that seem most promising have been selected for NIAID's Accelerated Vaccine Development Program. These include meningitis, hepatitis, respiratory diseases in children, diarrheal diseases, chicken pox, gonorrhea, influenza, whooping cough, genital herpes and malaria.

One exciting recent development has been the modification of the smallpox vaccine virus so that it protects against other diseases such as hepatitis and herpes. A live vaccine was first used by Dr. Edward Jenner nearly 200 years ago for protection against smallpox. It was the first effective vaccine, and its widespread use has driven the dreaded smallpox from the face of the globe.

Several years ago, Dr. Bernard Moss at the NIAID had the clever and inspired idea that the smallpox vaccine could be modified and used to fight other serious infections. For 15 years he had been doing research of the most fundamental sort on the virus; he knew his way around its internal machinery. Such basic research prepared him for the medical applications to follow. Dr. Moss is also a physician, and his mind was prepared to ask the question, "How can I use genetic engineering to modify this smallpox vaccine to protect patients against other diseases such as hepatitis and herpes?"

Progress is made by those who take such bold leaps to higher ground. Letting his imagination soar, Dr. Moss took bits of DNA from the hepatitis virus and stitched them into pieces of the smallpox virus. The experiment was a success. Animals immunized with the altered virus were resistant to subsequent exposure to hepatitis. Because these initial experiments with a genetically engineered vaccine have been successful, we are optimistic that it will be possible to vaccinate whole populations and to eradicate this form of hepatitis, still a dread disease throughout the world.

There is additional promise in this innovation of Dr. Moss. Perhaps, using his methods, we can alter the smallpox vaccine so that a single vaccination can protect against several different infectious diseases. Expanding on this research, other scientists recently reported that such a genetically engineered vaccine has prevented herpes in mice. It's even possible that a further modification can be used to prevent malaria, raising the exciting possibility that malaria, along with smallpox, might be wiped from the face of the globe.

There is a footnote to our recent achievements and Jenner's success in the prevention of smallpox. In 1796 Jenner's vaccination technique was greeted with great skepticism. But, undaunted, his bright mind tackled other unanswered questions in science. Shortly before his death, he published a study on ornithology in which he observed that robins, larks and other birds migrate with the seasons. Until then the disappearance of these birds in winter was attributed to hibernation in mud at the bottom of lakes and ponds. Such was the state of ignorance against which Jenner struck his blows to combat disease.

This committee has been generous in the support of basic research, even when it was difficult to show immediately how advances flowing from this support will benefit humankind. But the payoffs are now at hand. This success encourages us to redouble our efforts in the pursuit of basic research.

And yet even today, despite all our progress, we work against a background of ignorance just as Jenner did two centuries ago. The philosopher Leibnitz put the matter this way: "Since we live in an age which endeavors to go deeply into things, those who care for the general good must make an effort to take advantage of this tendency...." This Committee has followed the wise course and elected to "go deeply into things."

The budget request is $325,379,000, an increase of $11,269,000 over the comparable FY 1984 level. I would be pleased to answer any questions.

## BIOGRAPHY OF DR. RICHARD M. KRAUSE

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| POSITION: | Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health |
| BIRTHPLACE AND DATE: | Marietta, Ohio, U.S.A.<br>January 4, 1925 |
| EDUCATION: | B.A., Marietta College, 1947<br>M.D., Case Western University School of Medicine, 1952 |
| EXPERIENCE: | Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 1975 to present<br>(Assistant Surgeon General, U.S.P.H.S. Commissioned Corps, 1977 to present)<br>(Surgeon, U.S.P.H.S. Commissioned Corps, 1975-1977)<br>Professor, Rockefeller University, and Senior Physician to the Hospital, 1968-1975<br>Associate Professor, Rockefeller University, and Physician to the Hospital, 1966-1968<br>Professor of Epidemiology and Professor of Medicine, Washington University School of Medicine, 1965-1966<br>Professor of Epidemiology and Associate Professor of Medicine, Washington University School of Medicine, 1962-1965<br>Associate Professor, Rockefeller Institute, and Associate Physician to the Hospital, 1961-1962<br>Assistant Professor, Rockefeller Institute, and Associate Physician to the Hospital, 1957-1961<br>Assistant, Rockefeller Institute, and Assistant Resident Physician to the Hospital, 1954-1957<br>Internship and Residency Training, Internal Medicine, Barnes Hospital, 1952-1954<br>Research Fellow, Department of Preventive Medicine, Case Western University School of Medicine, 1950-1951 |

ASSOCIATION MEMBERSHIPS AND OTHER APPOINTMENTS:

Member, Scientific Advisory Committee of the Max-Planck Institute for Immunobiology in Freiburg
National Academy of Sciences of the United States of America, Chairman, Section 43, Medical Microbiology and Immunology, 1980-83
Institute of Medicine, National Academy of Sciences
Association of American Physicians
American Academy of Allergy
American College of Allergists
American Society of Clinical Investigation
American Society for Microbiology
Infectious Diseases Society of America
American Association of Immunologists
Royal Society of Medicine
Practitioner's Society of New York
American Rheumatism Association

American Thoracic Society
American Academy of Microbiology
American Epidemiological Society
New England Society of Allergy
American Society of Biological Chemists
The Harvey Society
Sigma Xi
American Association for the Advancement of Science
American Venereal Diseases Association
The Albert Lasker Medical Research Awards Jury, 1977
Member, Steering Committee of the Biomedical Sciences
Scientific Working Group, World Health Organization, 1978
Member, Board of Directors, Lupus Foundation of America, 1977
Member, Board of Directors, Asthma and Allergy Foundation of America, 1976-1977
Member, Infectious Disease Advisory Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 1970-1974
Board of Directors, Royal Society of Medicine Foundation, Inc., 1971-1977 (Treasurer 1973-1975)
Consultant and Member, Coccal Expert Committee, World Health Organization, 1967 to present
Directors Council, New York Heart Association, 1973-1975
Chairman, Allergy and Immunology Study Section, National Institutes of Health, 1966-1970
Commission on Streptococcal and Staphylococcal Diseases
United States Armed Forces Epidemiological Board (Deputy Director, 1968-1972), 1963-1972
Chairman, Research Study Committee and Member, Executive Committee, Council on Rheumatic Fever and Congenital Heart Disease, American Heart Association, 1963-1966
Member, Policy Committee, American Heart Association, 1966-1970
Board of Directors, New York Heart Association, 1967-1973
Chairman, Advisory Council on Research, New York Heart Association, 1969-1971
Chairman, Research Study Committee, Council on Rheumatic Fever and Congenital Heart Disease, American Heart Association, 1963-1966
Member, Executive Committee, Council on Rheumatic Fever, American Heart Association, 1963-1966
Member, Board of Trustees, Marietta College
Washington Academy of Medicine

EDITORSHIPS:

Section Editor, Journal of Immunology, 1974-1975
Editor, Journal of Experimental Medicine, 1973-1975

Editorial Board, Immunochemistry, 1973 to present
Editorial Board, Bacteriological Review, 1969-1973
Editorial Board, Infection and Immunity, 1970-1978
Associate Editor, Journal of Immunology, 1963-1971
Editorial Board, Clinical Immunology and Immunopathology, 1976-1978
Advisory Editor, Journal of Experimental Medicine, 1976 to present

AUTHOR:

Publications of more than 125 papers on research in infectious diseases and immunology

AWARDS AND HONORS:

Honorary Doctor of Science Degree, Marietta College, Ohio, 1978
DHEW, Distinguished Service Award, 1979
Honorary Doctor of Science Degree, University of Rochester, New York, 1979
Republic of Egypt Order of Gumhuria Award, 1980
C. William O'Neal Distinguished American Service Award, Marietta, Ohio, 1981
Honorary Doctor of Science Degree, Medical College of Ohio, Toledo, Ohio, 1981
Fellow, American Association for the Advancement of Science, 1982
Distinguished Alumnus of the Year Award, Case Western Reserve University School of Medicine, Cleveland, Ohio, 1982
Honorary Doctor of Laws Degree, Thomas Jefferson University, Philadelphia, Pennsylvania, 1982
Honorary Doctor of Science Degree, The Hahnemann Medical College and Hospital of Philadelphia, Pennsylvania, 1982

## OPENING REMARKS

Dr. KRAUSE. In regard to the sweepstakes question asked by Senator Proxmire concerning the areas where the decrease in morbidity and mortality have been the greatest, I would remind the NIH staff on this side of the table, as well as on the Senate side that the forerunner of the NIAID was the old Hygienic Laboratory and that gave birth to all the other NIH institutes. [Laughter.]

Despite this parentage, sir, we do not take credit for all the accomplishments of our offspring, but rather are the proud parents and admire what they have succeeded in doing.

Since 1900, when we—either NIAID or our forerunner, the Hygienic Laboratory—have been in existence, our research has led to a tremendous decrease in morbidity and mortality. Longevity has increased from roughly 39 to 40 years at the turn of the century to the biblical three score and ten today.

But despite all this progress, even today, 20 percent of all patients who seek medical care, who go to see a doctor, do so for what is clearly an infection. Those are national data, not our own. Infections are frequent causes of complications of chronic diseases and increase the length of time that patients are hospitalized. Patients with chronic diseases seek medical care because of frequent infections. Infections are the frequent cause of death of these patients. Finally, you've heard today—and we've participated in those studies—infections are thought to contribute to the cause of chronic diseases such as arthritis, AIDS, and many more.

Now, all these grave matters, of course, have been swept under the rug in recent years. I must say in the last 9 years that I've been before this committee, I've felt a little bit like a Don Quixote tilting windmills; but then my good friend, Dr. Lewis Thomas, finally came to my defense a year ago in an essay in which he said the following:

> Just a few years ago, in an excess of hubris, I wrote an essay in which I predicted that we were nearly finished with the problem of infection, and that only a handful of still unsettled matters were left to be tidied up here and there. Moreover, I took the stand that our microbial adversaries made up a finite, short list; once done with those still at large, I saw no reason to imagine the existence of others still unknown, waiting in the wings for their turn to get at us.
>
> I take it back. We are not about to finish the job of infectious disease, nor are we likely to in the near term, maybe not in the long, long term.

He did not say so, but his remarks could have been a reason to have an NIAID.

Several years ago I wrote a book that I'll summarize very briefly. [Laughter.]

There are several reasons why this is so, and I'm very glad that Dr. Lewis Thomas agrees with me.

First of all, the fortunes of microbes are enhanced by unexpected events and influenced by geographical and social forces—the plague in the 14th century, tuberculosis in the industrial revolution, sexually transmitted diseases in the recent 20 years of changing social habits in this country and elsewhere, and finally, of course, tropical medicine in which you have a tremendous interest in the countries beyond our shores including Latin America and Africa.

Second, microbes have learned to successfully negotiate the dangerous shoals of extinction by navigating through the unrelenting tide of evolution. For example, 40 years ago we could treat gonorrhea and many other diseases with penicillin. Today, penicillin is no longer effective for treating a score of common microbes that cause both illness and death. This successful struggle for survival through evolution means that such microbes will be a persistent challenge.

Third, and finally, microbes have an overwhelming advantage over humans because of what I have called the generation gap. That's not the same generation gap that the sociologists talk about, the gap between our generation and the young.

By generation gap I refer to the difference between the reproduction time of microbes and people. Microbes reproduce every 30 minutes; humans every 20 years. As a consequence, in the microbial world a civilization can rise and fall in a season—witness a flu epidemic; whereas for humans, a civilization rises and falls in a millenia. Is it any wonder, then, that microbes can run circles around us and survive? What do we do about that?

Well, one thing is to develop better and additional vaccines; and this I have described in detail in the submitted statement. We will use new recombinant DNA technology and hybridoma monoclonal antibodies to develop a whole new array of vaccines.

We've developed 12 vaccines in the last 100 years. Our goal is to develop at least 10, if not more, in the next 10 years. In other words, a tenfold increase in the pace of vaccine development.

I believe we can do that.

Let me end on an historical note, which is a matter of interest. Smallpox vaccine was introduced 200 years ago by Dr. Jenner, as you know. We think we can take that smallpox vaccine, which has been used to wipe smallpox from the face of the globe, and with genetic engineering change its internal aspects so that we'll protect against malaria and herpes, hepatitis, and many more diseases.

Imagine that; to do away with malaria as we've done away with smallpox. But a note about Jenner.

He retired amid considerable controversy about his vaccine, but his retirement was a happy one. He turned to ornithology and proved that, in fact, robins and mudlarks and other birds did not hibernate over winter at the bottom of ponds in England, but indeed, migrated to the south; a major scientific achievement at that time. Imagine the ignorance against which he was working, the belief that birds hibernated in the winter at the bottom of ponds rather than migrating.

You've been generous, Mr. Chairman and this committee, in the support of basic research. We thank you for that. It's often difficult to show how basic research will pay off in the long run. The payoffs are now at hand. You've heard about that all morning.

But, despite our progress, we still work against a background of ignorance just as Jenner did. You'll recall that ignorance. It was unknown that birds migrated south during the winter.

In regard to the support of basic science, the philosopher, Leibnitz, put it this way: "Since we live in an age which endeavors to go deeply into things, those who care for the general good must make an effort to take advantage of this tendency."

Mr. Chairman, you and this committee have followed Leibnitz' wise advice and have elected to go deeply into things.

I will be pleased to answer any questions.

### DEPARTURE OF DR. KRAUSE

Senator WEICKER. Thank you very much, Dr. Krause.

First of all, where are you going?

Dr. KRAUSE. I'm going to migrate south,—[Laughter.]—along with the mudlarks, to Emory University where I will be dean of the medical school in Atlanta as well as a Woodruff professor of medicine, which is an endowed chair.

### 1985 PRESIDENT'S BUDGET

Senator WEICKER. We wish you well. I think it's a great commentary, I might add, on you and on the fine people that we have at NIH wearing this type of a hat.

I might add, also, in some ways the handwriting on the wall is, I'm sure, what any of you gentlemen could do because Government is very clearly the beneficiary of your willingness to serve in positions that don't get either the recognition or the pay.

I think it's a happy situation for Emory and clearly a loss for NIH. I wish you well.

Where will the President's budget impact most harshly on your Institute?

Dr. KRAUSE. I would say that the impact will fall in several areas. First of all, the keel, the vital force of the NIH as a whole is the free ranging research done by individual research grants, and the President's budget will result in a decrease of nearly 80 competing research project grants over the last 2 years.

That's the first area; and those grants will not be fully funded. They will be reduced about 7.3 percent from projected study section recommended levels. So we will be funding fewer competing investigators. Of course, those are often the younger investigators attempting to get into the field.

Second, there will be a major cut in research and development contracts. Indeed, the budget for research and development contracts this year is approximately the same as it was in fiscal year 1978. Therefore, this represents a considerable buying power dollar loss for R&D contracts in view of inflation.

Senator WEICKER. I'm sorry. My mind was wandering. Would you repeat that again, please?

Dr. KRAUSE. I said, the budget for research and development contracts is essentially the same as in fiscal year 1978. The reason for this is, of course, that in order to maintain the momentum in research grants, we have placed the highest priority on that mechanism. Furthermore, we are requesting additional funding for the Intramural Research Program to initiate and augment development of vaccines for hepatitis, rotavirus diarrhea, and pertussis.

A third area which I think is very important is training. There will be a decrease in the number of trainees, as there has been over the last 9 years since I have been in the Institute. So it goes from one institute to the next, but let me say that this decrease in training has been a trend which I think is an ominous one.

### ACQUIRED IMMUNE DEFICIENCY SYNDROME [AIDS]

Senator WEICKER. Would you like to give us an overview of your work in the matter of AIDS?

Dr. KRAUSE. Yes, sir; there are several areas that are extremely important.

First of all, we must understand the routes of spread of this disease. While a good deal of attention has been given to the spread of disease among groups with certain sexual preferences, it is quite clear that it is also spread among other groups, in high risk groups other than those individuals. It is very important that we understand how this disease is spread in the community, just as is the case for any other infectious disease.

Second, it is very important that we identify the infectious agent that causes this disease. Dr. DeVita has already spoken to this. We, too, are also casting a wide net to identify the putative infectious agent.

Third, even if we discover the infectious agent, we may not be able to treat it if it is a virus because we have very few antiviral drugs, and it may take some years to develop a vaccine.

We must understand the nature of the defect(s) in the immune system in AIDS, and then learn how to correct such defect(s) by some appropriate drug or other manipulation.

We are looking very hard at what is wrong with the immune system in these individuals. The goal is to correct the abnormality in some way. In order to do this, we have clinical trials underway at the clinical center using interferon and other hormone-like substances of the immune system such as interleukin-2. I am optimistic that we will find something that will be effective.

Remember, this is true for many chronic diseases. We have found a way to manage many chronic diseases so that people can live an active and quite healthy life, despite the fact that we have not cured the disease. Examples include the use of insulin for diabetes and the use of cortisone for rheumatoid arthritis. I am optimistic that we will find some such way to assist patients with AIDS so that they can live reasonably normal and healthy lives.

Finally, it is very important that we understand much more about the strange infections that are actually the cause of death of these patients. These patients die from unusual infectious agents—opportunistic infections. We must learn more about them. We have a good program to do that, and to find drugs which can be used to treat these unusual infectious agents.

## MALARIA

Senator WEICKER. Last—and there will be other questions for response to the record—the matter of malaria. I know you pointed this up on my visit to NIH, and you mention it again today.

How close are we to eliminating malaria?

Dr. KRAUSE. I think that it will take a major concerted effort over the next 10 years, but I am optimistic in the next 10 years we will see tremendous inroads. We are committed to it. You have seen what we have done and are doing at the NIH. The World Health Organization is also committed to it.

From our own laboratories out at the NIH is the recent development of the first malaria vaccine by genetic engineering. It is being used in animals, not yet in humans, but at least it looks promising. So I think we have the prospect of a vaccine. Five years ago I would have never thought this would be on the horizon. That is how fast the field is moving.

Second, through the application of modern biological techniques, I believe we will be able to do much more in the control of the mosquitoes—the insect vector that spreads the disease—than we were able to do in the past. That is extremely important for the control of malaria.

So I think prevention through vaccines and prevention by controlling the mosquito population are two important avenues that we now have that we did not have 5 years ago.

Senator WEICKER. How much do you have in your budget for research in the malaria area?

Dr. KRAUSE. The total tropical medicine budget is about $33 million in the present budget, and of that about $4 million would be for malaria.

Senator WEICKER. What could you use in the area of malaria—reasonably, meaningfully use?

Dr. KRAUSE. I think that we could use additional resources in malaria as well as in tropical medicine. But we would have to scale up, because that has not been an area that has been well funded. Therefore, it has not been an area that has attracted enough of the best and the brightest people.

A wise expenditure of money in tropical medicine would require scaling up and not a sudden major increase in 1 year. We would have to develop over a 5-year period a larger cadre of investigators who could count on sustained support. Then I have no doubt that we would find young people who would be prepared to make that commitment, because the problems scientifically, from the health point of view, from the medical point of view, and from the humanitarian point of view are overwhelming.

Senator WEICKER. It seems to me that most of the emerging nations of the world are in the tropical areas. It seems to me also that this is the great battleground in terms of ideology among the various superpowers.

Therefore, it seems to me that it would be a very small price to pay for us to advance our knowledge in this area and have it as a benefit, as a plus.

Dr. KRAUSE. To specifically answer your question, I think that if the tropical medicine budget were to increase by 20 percent a year over a 5-year period—it would more than double over a 5-year period—that would give time to develop the new young group of people who could then man this area.

Senator WEICKER. So what you are talking about is about a $6 million increase this year in the tropical disease budget?

Dr. KRAUSE. Yes.

Senator WEICKER. Do you think that is possible, Mr. Itteilag?

Mr. ITTEILAG. Well, Mr. Chairman, the Congress obviously has the last word, or nearly so, on appropriations.

Senator WEICKER. Wait till you take your next trip to Africa. [Laughter.]

No, I am sorry, I don't mean to be facetious, Mr. Itteilag. Make no mistake about it. I have come to the conclusion that after last year's rounds of budget hearings I think Mr. Itteilag's heart is clearly in the right place, and it is very unfair for me to come down on him.

Dr. Krause, thank you very, very much. We will have other questions for response to the record.

Again, I thank you for your wise counsel the couple of years that I have been in this chair, we will miss you, and the best of luck to you.

### DEPARTING REMARKS

Dr. KRAUSE. May I make just a brief statement, since my leaving the NIH did come up?

I have been here nearly a decade. It has been one of the great decades of my life. I have not had a better time anywhere, nor a more creative time anywhere in my professional career, and I have been in some notable institutions, including Rockefeller University and Washington University. It has been my privilege to serve with great NIH Directors—Dr. Donald Fredrickson, Dr. James Wyngaarden, and Dr. Thomas Malone as acting NIH Director, and also great Assistant Secretaries for Health, Dr. Theodore Cooper and Dr. Edward Brandt.

It has been a pleasure to work with this committee and the committee in the House. I go with a heavy heart, but at the same time I think administrators ought to move on from time to time, and let someone new take over the helm of an institution. Furthermore, this is really a new opportunity for me.

But the NIH is still one of the great places for research, and it will continue to be not only in the United States but in the world at large. You take care of it. You and Mr. Itteilag will help take care of it. [Laughter.]

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you. Thank you very much. The additional questions will be submitted to you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget--small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget--or were you simply handed a number and told to find ways to live within it?

Answer: I, along with the other BID Directors, was consulted at the time of every major submission in the budget process. In conjunction with Dr. Wyngaarden, we set overall NIH priorities given the NIH allowance at the various stages, albeit with diminishing flexibility the closer we got to the President's Budget.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: Within the funds available, we will make every effort to maintain the scientific momentum of our various research programs. We will be able to support 444 competing research project grants at an estimated payline of 160, to fund the same number of research centers as in FY 1984, to support 14 competing research career awards, and to provide a modest increase in the Minority Biomedical Research Support Program. Although funding for R&D contracts is below the FY 1984 level, we will provide additional funding to the Intramural Research Program in order to fully support ongoing AIDS research as well as high priority vaccine development activities related to hepatitis B, rotavirus diarrhea, and pertussis.

Question: To what extent will your new and continuation grants be funded below full cost levels--and what important research will be delayed or eliminated as a result?

Answer: Noncompeting and competing research project grants will be reduced below projected study section recommended amounts by 7.6 and 7.3 percent, respectively. Reduced funding by NIAID resulting in a decrease in the size of the grant means that the investigator must make very hard choices about following new leads and opportunities. We hope our grantees will share in this effort to cut costs in ways that will be the least disruptive to their research programs. We will work closely with our grantees to make every effort to minimize the impact of these reductions.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84? What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: In order to maintain the same number of research centers supported in FY 1984, we will reduce support by about 3 percent below projected study section recommended amounts. Fortunately, a few of our centers have projected recommended levels for FY 1985 below those recommended for FY 1984, so overall reductions required are not substantial.

Less than full funding of the centers may retard, to some degree, the speed with which basic research findings are translated into new methods of preventing, diagnosing, and treating disease. The centers funded by our Institute play a vital role in clinical research on diseases of the immune system and on immune-related diseases such as allergies. By coordinating its resources, each center plans an interdisciplinary approach to a particular disease or group of diseases. Scientists from diverse disciplines have access to sophisticated facilities and equipment and to an appropriate complement of patients for study and long-term follow-up. The organization of these centers encourages active scientific communication, which tends to maximize the opportunity for the development of clinically applicable methods. The centers also provide an avenue for the dissemination of knowledge gained through basic and clinical research to primary care physicians and patients.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: Under the President's Budget the Institute will support 440 full-time training positions, a reduction of 12 from FY 1984. A continuing trend downward would retard our ability to continue to attract our finest young people into careers in science and thus could impact the future of biomedical research in allergy, immunology, and infectious diseases.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: The calculated current services budget for the Institute is $349,998,000, an increase of $24,619,000 over the President's Budget.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction--and where will you take it? With what effect on research?

Answer: In FY 1985, the NIAID budget request includes 710 full-time equivalents (FTEs). The NIAID's portion of the 588 FTE reduction is 32. Twenty-eight will be taken from the Intramural Research Program and four will be taken from Research Management and Support. It is difficult to assess the precise impact these reductions will have on our programs. The Institute will attempt to implement the reductions in a way that minimizes the impact on research in progress and on the effective management of our organization.

## AIDS RESEARCH

Question: Your Institute, Doctor, has a major responsibility for research on AIDS. Are we making any progress against this terrible disease and is the present level of funding sufficient to the task, in your professional judgment?

Answer: We are making steady progress in our study of Acquired Immune Deficiency Syndrome (AIDS) as demonstrated by our wide range of research activities: a number of viruses are under active investigation that may turn out to be the cause of AIDS; a major study in five different cities of the natural history of the disease has begun; attempts are being made to develop tests to detect AIDS early in its course; extensive studies to understand the exact nature of the immunologic abnormalities in AIDS patients are being supported; clinical trials to attempt to reconstitute the failed immune system are being conducted and have some preliminary exciting results; studies of the basic biology of the unusual microorganisms that cause the opportunistic infections which kill AIDS patients are being supported; and the development of new drugs for the treatment of these infections is being funded.

NIAID funding for AIDS was $9.223 million in FY 1983 and increased by about $5.5 million in FY 1984 to a level of $14.720 million. In my professional judgment, if we are to take advantage of scientific breakthroughs as they occur, additional funding would be well spent.

Question: Please bring us up to date on what you are doing to identify the cause of AIDS and to trace its natural history.

Answer: NIAID recently funded nine new cooperative agreement grants attempting to identify the cause of AIDS, totalling over $1 million for the first year. NIAID has also been supporting 17 other research projects grants on AIDS totalling $2.8 million.

Simian acquired immune deficiency syndrome (SAIDS) is being studied in monkeys as a model for AIDS. Although SAIDS is clinically similar to human AIDS, some features clearly distinguish each from the other. Recently, the agent associated with SAIDS was isolated and identified as a type D retrovirus. Inocula containing this virus produced SAIDS in susceptible monkeys. It is noteworthy that one of the candidate agents for causing human AIDS is also a retrovirus, and this is being pursued diligently.

The NIAID intramural program is involved in various efforts to determine the etiologic agent of AIDS. A contract with the New York Blood Center and the Memorial Sloan Kettering Cancer Center is designed to follow a large number of individuals considered to be at high risk of acquiring AIDS. Various body tissues and fluids are being collected and stored; in the event that individuals participating in the study acquire AIDS, stored specimens will provide valuable resource materials for examination as to etiologic agent. In addition, five contracts in the NIAID extramural program are set up to follow similar populations. Specimens from these contracts will also be stored along with the New York specimens in a repository of the Intramural Research Program (IRP). The specimens from the New York contract are already being studied by a number of laboratories within the IRP that have expertise with a range of bacterial, fungal, and viral agents to determine if any of these agents can be found in the specimens or if antibody to any candidate agents are present. The NIAID IRP is also planning to support, via contract and with intramural personnel, a study of AIDS in Zaire. The high incidence of disease in that country and its somewhat different epidemiologic pattern may provide important information.

We have awarded contracts totalling over $2 million per year to study the natural history of AIDS in homosexual men in Berkeley, California; Los Angeles, California; Chicago, Illinois; Pittsburgh, Pennsylvania; and Baltimore, Maryland. The purpose of these projects is to observe and study the natural history of biological events in the lives of homosexual men at risk of developing AIDS. We plan to study the natural history of the disease in enough persons who are uninfected at the outset to yield a number of cases of AIDS sufficient for meaningful estimates of risk, and to build a repository as a national resource for specimens and data from men who traverse the entire course from well to ill.

We have also funded three cooperative agreements dealing with different facets of AIDS epidemiology and natural history. Dr. Arye Rubinstein, Albert Einstein School of Medicine, Bronx, New York, is following drug addicts with AIDS and their family members for possible spread of the disease within families. This work includes intensive study of children with AIDS. Dr. Michael Lange at St. Luke's-Roosevelt Medical Center in Manhattan is following over 100 homosexual men at high risk for AIDS to determine whether any immunological, biochemical, and clinical changes occur in these men that may provide early clues about the development of AIDS. Dr. Lange has followed these men for nearly 3 years now and will continue to do so for 2½ years more with our grant support. Dr. Pearl Ma at St. Vincent's Hospital in Manhattan is studying the epidemiology of cryptosporidiosis in AIDS, a newly described parasitic infection of the bowel that produces severe diarrhea and weight loss in AIDS victims.

Question: You apparently are planning to establish a repository for tissues and fluids from AIDS patients and from those at risk of developing the disease. How far along is this effort and how do you plan to use it?

Answer: Contracts supporting longitudinal studies on the development of AIDS were awarded to institutions in five metropolitan areas in September 1983. During the past 6 months, plans have been made to collect detailed epidemiologic data and biologic specimens, largely according to a common protocol, from approximately 1,000 homosexual men in each area. These materials will be collected from each man being followed every 6 months over the next 3 years, and considerable clinical, laboratory, and epidemiologic analysis will be performed at each of the centers. Biological specimens will be stored locally; in addition, at least 50 percent of each specimen will be transferred to a control facility for separate storage.

Varied uses may be made of the materials that are collected from the study subjects and stored. One important objective of the repository is wide and easy access. Any serious investigator with a promising idea and an appropriate collaborative research plan should be able to draw upon the material in the bank. An investigator may search for the presence of a presumptive causal agent or for evidence that infection with such agent has occurred at some time. Another might inquire whether, in different forms or at different stages of the infection, the agent may be present in different body fluids. Sequential specimens should permit observations on the changes in immunity over time. The repository will allow comparison of risks for immune alterations according to differences in behavioral factors and comparisons of the effects of similar exposures in the different study locations. In short, the repository promises to be a versatile and valuable resource for the study of homosexual men at risk for AIDS.

We have already established a repository in the intramural program in which specimens from the intramural contract with the New York Blood Center as well as specimens from the five extramural contracts will be stored. We have been receiving specimens from the intramural contract since November 1983, and specimens from this contract have already been provided to a number of intramural scientists for their studies on etiology and on possible diagnostic procedures. We anticipate that we will begin receiving specimens from the extramural contracts in the next few months. Specimens stored prospectively from participants who eventually develop AIDS will be particularly valuable. So far, one participant in the study has developed the disease.

Question: We note you are conducting therapeutic trials to attempt to reconstitute the failed immune system that is a major manifestation of AIDS. What success are you having?

Answer: The NIAID Intramural Research Program has been involved in four treatment protocols using various approaches to the reconstitution of the immune system. One protocol involved the attempted immune reconstitution using bone marrow transplantation to an AIDS patient from his identical, healthy twin. Although there appeared to be clinical and immunologic improvement, the patient died of pneumonia. No similar opportunity has recurred. Two other protocols involve the use of the immune system hormone-like substances, interferon and interleukin-2, for the treatment of AIDS. Both of these compounds have clearly caused some improvement in the immune systems of patients; however, it is too early to say if treatment of AIDS with interferon or interleukin-2 will completely restore the immune system to normal. These studies are being continued and are being expanded to a limited degree.

The fourth NIAID treatment protocol involves the use of plasma exchanges to remove possible suppressor substances from the blood of AIDS patients. One patient was begun in FY 1983, and there are plans to add additional patients to this protocol. No clear results are available at the present time.

## IMMUNOLOGY

Question: We recently read of David, the "Bubble Boy" who lived in a plastic tent and later died. I gather that the basic problem was an immune deficiency. What did that experience tell us about our understanding of the immune system and how far we still have to go in mastering the medical problems that relate to it?

Answer: David's basic problem was an inborn immunodeficiency that left him without a functional immune system and, consequently, extremely vulnerable to infection. He could survive only in the germ free environment of the bubble, and his only hope for acquiring a functional system was through some type of immunologic reconstitution.

David's condition was not unique; it occurs approximately once in 50,000 births. Experiments to reconstitute immunodeficient children have been underway for several years. The experience with David clearly indicates that we still need a better understanding of abnormalities in the immune system and the means to correct them. In David's case an attempt was made to reconstitute the immune system by bone marrow transplantation. Bone marrow transplants are often successful when there is a perfect match available from a parent or sibling. In this case, no perfect match was available and the transplant was made with an imperfect match using various procedures to inhibit cells aiding in the rejection and to enhance stem cell production. Unfortunately, this approach was not successful in this case. Although we have learned a great deal, we have a long way to go in determining the procedures necessary to reduce the numbers of cells that cause graft rejection. Studies of cell populations using various new reagents such as monoclonal antibodies should lead to advances in this area.

Question: What about bone marrow transplants--are those a realistic solution to the problems of immune deficiency?

Answer: For David's type of immune deficiency, transplantation of bone marrow represents a practical approach for immunologic reconstitution. Unfortunately, in David's case, no bone marrow donor who exactly matched David could be found. In transplanting unmatched bone marrow, the major problem is that the donor bone marrow graft will develop an immune response within the recipient and attack the recipient's own tissues. The availability of a monoclonal antibody, developed through hybridoma technology and able to destroy only the aggressive mature cells in bone marrow, made it possible to attempt an immunologic reconstitution for David using mismatched bone marrow. This approach has not yet been perfected, but it has been successful in a few patients.

When there is a perfect match, bone marrow transplants are very useful. As we gain additional information about the cells involved in rejection of bone marrow transplant grafts, the ability to improve grafts in the case of imperfect matches will increase. This technology is improving and does appear to represent a realistic solution in the future.

Question: Are there substantial research opportunities in this field that await us if only we have the will--and the money--to go forward?

Answer: In immunology, which encompasses the field of bone marrow transplantation, there are many opportunities that await us, as we have indicated in the report on immunology research. Advances in our understanding of the fundamental molecular and cellular mechanisms of the immune system as it functions in health and disease are providing exciting new leads. We are now just beginning to comprehend the complexity of the interactions between the cellular elements of the immune system, of the immunoregulatory effects of their products, and of the genetic influences on the system. We still need much more insight into the nature of the immune system's involvement in disease before specific interventions or application of the fundamental knowledge can be developed. The problem of AIDS is just one example in which more understanding of the immune system's function is required to develop appropriate therapeutic and possible preventive measures. I suspect that we are almost halfway in achieving knowledge to selectively manipulate and master the immune system.

## CUT IN CONTRACTS

Question: I note that the proposed budget would hit you with a $3,106,000 cut in your research and development contracts. What effect would this have on your ability to develop vaccines for sexually transmitted diseases, meningitis, malaria and other diseases?

Answer: The proposed $3,106,000 cut in R&D contracts would affect other contract-supported activities such as those in rapid viral diagnosis, leprosy, and croup in addition to vaccine development. Infectious diseases targeted for our Accelerated Development of New Vaccines program include meningitis, gonorrhea, genital herpes, viral respiratory infections caused by respiratory syncytial virus and parainfluenza viruses, whooping cough, influenza, chickenpox, hepatitis, diarrheal diseases, and malaria. The reduction in the contract program would impact our efforts to test new products in Vaccine Evaluation Centers, retard other efforts currently in progress, and curtail new contract activities in vaccine development. However, the proposed budget includes additional funding for the Intramural Research Program to augment development of vaccines for hepatitis, rotavirus diarrhea, and pertussis.

Question: How far along are we toward successful development of such vaccines? In your professional judgment, will the restoration of $3,106,000 make you whole in this effort, or will it take more than that amount?

Answer: The NIAID has identified a number of infectious diseases for its Accelerated Development of New Vaccines program. A large-scale efficacy trial for a new Hemophilus influenzae type B vaccine is underway. The vaccine will be evaluated for its ability to protect infants against H. flu meningitis. A candidate gonococcal vaccine has reached the point where a field trial is being performed to assess its potential for protection against gonococcal infection. A new, improved B. pertussis (whooping cough) vaccine will undergo early clinical testing in the near future. A live vaccine for rotaviruses has been developed by NIAID intramural scientists and is currently being evaluated in adult volunteers. Future trials are planned for children and infants. The NIAID contributed significantly to the development of the currently licensed hepatitis B vaccine. Efforts are underway to develop a "second generation" vaccine that will be less expensive. Clinical trials for safety, immunogenicity, and efficacy will need to be undertaken before licensure is considered. A live attenuated hepatitis A vaccine is currently under development and animal model studies suggest that this is a feasible approach to prevention of this infectious disease. NIAID scientists and contractors have been successful in developing a new live, attenuated influenza vaccine. This vaccine, administered as "nose drops," is undergoing field trials. Research efforts for a malarial vaccine continue to be productive, and materials should be available for pilot studies within the next year.

We are in the midst of exciting times for vaccine development efforts for infectious diseases. The promises of recombinant DNA and monoclonal antibody technology are now bearing fruit. New vaccines resulting from these new technologies are being developed in the laboratory, but these vaccines will require clinical testing before they become available to the public. Restoration of the reduction will help, but will not make our efforts whole. We have $11.05 million targeted for the Accelerated Development of New Vaccines program in FY 1985, but this amount is really minimal. In my professional judgment $14.14 is required for a truly accelerated effort.

## SEXUALLY TRANSMITTED DISEASES

Question: While AIDS is now a major worry, the Subcommittee continues to be concerned about the efforts to combat other sexually transmitted diseases, which your justification describes as a "major public health problem." Can you bring us up to date on what progress you are making to develop vaccines against genital herpes and other sexually transmitted diseases?

Answer: A candidate gonococcal vaccine is in field trial, and Group B streptococcal candidate vaccine should be ready for a field trial in the near future. With other research, progress is being made and our knowledge in these areas is continuing to expand.

Based on a strong NIAID program of basic research on herpesviruses over the past several years, a number of approaches to develop vaccines against genital herpes have emerged. The most promising to date are genetically engineered, live, attenuated vaccines that show promise of protecting against infection by both the type 1 and type 2 viruses that are associated with oral-facial herpes and genital herpes, respectively. Initial clinical trials of candidate vaccines are anticipated in the near future to test for safety and antigenicity.

Two other new approaches also involve molecular genetics. One is the production of immunizing antigens of herpesviruses by recombinant DNA cloning and expression in bacteria. The other involves inserting herpesvirus genes in vaccinia virus and immunizing as was formerly done for smallpox. The last two approaches have shown successful protection in animals but have not yet been tested in humans.

Question: Your justification mentioned the development of new diagnostic tests "requiring only 15 to 20 minutes" to identify infections from sexually transmitted diseases. How reliable are these tests and are they generally available to medical practitioners?

Answer: The most rapid test available is a direct immunofluorescence test. A specimen is smeared directly on a slide, stained with reagent containing flourscein-labeled monoclonal antibodies and a counter stain, and then read using a flourescence microscope. This test for the identification of Chlamydia trachomatis is being marketed by the SYVA Co., a subsidiary of Syntex. They are working on a similar test for herpes, gonorrhea, and syphilis and hope to have the test for herpes on the market by fall. Other companies have developed or are developing enzyme immunoassays (EIAs) for the detection of sexually transmitted disease agents. These companies include Abbott Laboratories, Ortho Diagnostics, and Electronucleonics, among others. The EIAs take between 1 and 5 hours to perform. Most of these tests, immunofluorescence and EIA tests, are 75 to 90 percent sensitive and 90 to 98 percent specific. They are being performed in large hospitals and diagnostic laboratories right now. Improvements in the tests are still sought in order to increase the sensitivity without losing the specificity. Although the tests are not as sensitive or as specific as culture of the organism, they are much faster and cheaper, and will probably replace many of the standard tests that involve culture of the organism.

Question: What can you tell us about reports indicating an increasing incidence of herpes cases in newborns? What can be done to help these children?

Answer: Some investigators perceive an increase in the incidence of herpesvirus infections in the newborn. However, since it is not required that cases of herpes be reported, no solid data base exists to support such a conclusion. There is certainly concern about genital herpes infections and the transmission of disease to the infant at delivery.

Treatment of neonatal herpes simplex virus infection is currently being studied in a large collaborative clinical trial supported by the NIAID. This study is testing the efficacy of the new drug acyclovir compared to the older drug vidarabine. Earlier studies have shown that vidarabine is an effective agent in reducing both mortality and morbidity associated with this disease.

## OTHER AIDS QUESTIONS

Question: We're advised that AIDS may have occurred in Africa prior to its appearance in this country. What plans have you made to conduct studies of AIDS in Africa--and have you done any preliminary work on the matter in that area of the world?

Answer: Within the next 3 months, the NIAID expects to award a contract to do studies on AIDS in Zaire including the nature of the disease, its epidemiology and possible etiologic agents. In addition to the contract, the NIAID intramural program will have a staff member on site. The NIAID contractor and staff member will also be collaborating with CDC staff stationed in Zaire. Prior to the start of this project, NIAID researchers have made two trips to Zaire and, in collaboration with CDC staff, have shown that the incidence of AIDS in Zaire is very high and that it affects different populations than in the United States. In addition, samples returned from these trips are being intensively studied by NIAID researchers.

Question: We're told that "interleukin-2", a natural immune system regulating substance, may have some positive impact on the immune system cells from AIDS patients. What can you tell us about this?

Answer: Interleukin-2, as well as interferon, another immune system hormone-like substance, is being used in clinical studies in the NIAID to determine their value in treating deficiencies of the immune system in AIDS patients. Although interleukin-2 and interferon clearly have caused some improvement in the immune systems of patients, it is too early to say if treatment of AIDS with these compounds will completely restore the immune system to normal.

## REYE'S SYNDROME

Question: Reye's syndrome is a life-threatening illness that affects children under the age of 18. We're told the syndrome can lead to long-term complications, such as mental retardation, palsy and motor dysfunction. Where do we stand in the effort to find the cause of Reye's syndrome?

Answer: The cause of Reye's syndrome is still a mystery. In the last several years research on Reye's syndrome has revealed that the cause of this disease is likely to be multifactorial. That is, various agents may need to interact to produce this disease. Certain viral infections, notably influenza A or B and chickenpox, are commonly associated with this disease. In addition, the use of certain medications, primarily aspirin, has also been associated with the disease. Current research efforts include basic studies on the associated viruses, identification of animal model systems, and the conduct of epidemiologic investigations to determine the relationship of medication use to Reye's syndrome.

Question: What have you learned about the possible role of aspirin in the cause of the illness?

Answer: Epidemiologic studies suggested that aspirin use was associated with the development of Reye's syndrome. This observation remains to be confirmed. A study of the role of medications and their possible association with Reye's syndrome is being conducted by the Public Health Service.

Question: What work do you do with other institutes--Neurology, for example--in supporting studies on the cause and treatment of the disease?

Answer: Research activities on Reye's syndrome have greatly benefited by the close cooperation and interaction between institutes at NIH. A working group on Reye's syndrome was established by the NIH Director in 1979 and remains active. This group exchanges information and has cooperated in a series of Reye's syndrome activities. A joint program announcement soliciting research applications in Reye's syndrome was published in May 1980. Also, a consensus development conference on the diagnosis and treatment of Reye's syndrome was held in 1981. The primary responsibility for the organization of this conference resided with NINCDS; but other components of NIH, including NIAID, actively assisted NINCDS in the planning and conduct of this conference. In addition, all components of NIH are providing financial support for the study of medications and Reye's syndrome, which is currently underway under the direction of the Public Health Service Task Force on Reye's syndrome.

## ALLERGIES

Question: There apparently is controversy over the use of food extracts for the diagnosis and treatment of food allergies. The Health Care Financing Administration, for one, believes they may not be safe and effective. What can you tell us about this research and the controversy that seems to have sprung up around the matter?

Answer: In 1981 the National Center for Health Care Technology published a series of "Assessment Reports" concerned with the diagnosis and treatment of food allergies. Specifically addressed were the use of the cytotoxic leukocyte test for diagnosis, the use of sublingual provocative and neutralization treatment for food allergies, and the use of intracutaneous and subcutaneous provocative and neutralization testing and treatment for food allergies. It was concluded that insufficient evidence existed to confirm effectiveness of these techniques for the diagnosis and treatment of food allergies. Subsequently, various professional and lay organizations, including the American Academy of Allergy and Immunology and the Asthma and Allergy Foundation of America, distributed these reports, or a summary of the reports, to inform their constituents. In 1983, the Health Care Financing Administration, following deliberations of its advisory panel, issued a statement which concluded that these procedures were neither effective nor proven in the usual scientific manner and, therefore, proposed denial of reimbursement for their costs.

Question: To what extent do you support research into food allergenic extracts and their usefulness either as diagnostic tools or desensitizing agents?

Answer: Recognizing that the acquisition of relevant scientific data could clarify some of the questions pertaining to diagnosis and treatment of food allergies, the NIAID initiated several related research activities in this area. A panel of standard, well-characterized food extracts has been prepared for use in research studies on the diagnosis of food allergies. In addition, we have formed a Food Allergy Working Group involving research investigators at universities and research centers who meet periodically to review and compare data and devise relevant cooperative studies. We have also supported a number of individual research grants that were submitted in response to an NIAID Request for Applications focused on this problem; these investigators are also members of the Food Allergy Working Group. Furthermore, in collaboration with the American Academy of Allergy and Immunology, NIAID staff are preparing and soon will publish a comprehensive monograph summarizing and reviewing the current knowledge in this area.

Question: Do you coordinate your research with the Food and Drug Administration and the Health Care Financing Administration?

Answer: Standardized food extracts for research studies were developed in collaboration with the Food and Drug Administration and are being distributed with its approval as "investigational new drugs." Similarly, NIAID staff have provided requested information and assistance to the Health Care Financing Administration in its consideration of this issue.

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## QUESTION SUBMITTED BY SENATOR WILLIAM PROXMIRE

### OTHER POSITIONS

Question: I note that the Institute is projecting a significant reduction in its original estimate of 1984 full-time equivalent positions from 164 in last year's justification to a revised figure of 110 positions. Despite this reduction the budget estimate for 1984 positions other than full time was $3,689,000 last year but has been increased to $5,076,000 in your current justification. Can you tell us why the full time equivalent of positions other that permanent is going down while their cost is going up?

Answer: Through an oversight, an adjustment in the number of permanent and other than permanent full-time equivalent positions was made earlier in the budget process without a concomitant change in the funding associated with these positions. The funding should have been reflected as follows:

| | 1984 Estimate | 1985 Estimate |
|---|---|---|
| Personnel compensation: | | |
| Permanent positions............. | $19,996,000 | $20,638,000 |
| Positions other than permanent.. | 2,729,000 | 2,037,000 |

## NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

## STATEMENT OF DR. RUTH KIRSCHSTEIN, DIRECTOR

## ACCOMPANIED BY WILLIAM FITZSIMMONS, EXECUTIVE OFFICER

### BUDGET REQUEST

Senator WEICKER. All right, our last witness for today will testify on behalf of the National Institute of General Medical Sciences which focuses its research on fundamental biological structures, such as the cell and gene.

The budget request for the Institute is almost $424 million, $8.2 million more than the fiscal 1984 level.

Here to explain the request to us is the Director of the Institute, Dr. Ruth Kirschstein. We welcome you, Doctor. Please introduce your colleagues and proceed.

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman.

I would like to introduce Mr. William Fitzsimmons, the Executive Officer of the Institute.

Coming at the end of a whole morning, I find that much of what I had planned to say has already been said by my colleagues. I think that is, in some ways, particularly apt because the particular mission of the National Institute of General Medical Sciences is to foster the development of new knowledge, concepts, and technologies that are needed to make progress in the disease studies that are supported by the other components of NIH, the categorical institutes. The previous witnesses have told you about some of the progress made to date in the fight against diseases; and I have tried, in my written statement, to tell you about some of the research supported by NIGMS that will facilitate such progress in the future.

### NOBEL PRIZEWINNERS

We are very proud at NIGMS that over one-half of the 85 NIH-supported Nobel prizewinners have had grants from our Institute. This impressive record continued this year when a longtime grantee, Dr. Henry Taube of Stanford University won the Nobel Prize for his studies concerning the mechanism of electron transfer between biochemical compounds.

As you know, Mr. Chairman, because you were present at the award ceremony, another grantee of NIGMS, Dr. Eric Kandel received the prestigious Albert Lasker Basic Medical Research Award this year for his studies of the cellular mechanisms of learning.

### BASIC BIOMEDICAL RESEARCH

As my colleagues told you this morning, I will repeat that the modern era of biomedical research started just over 30 years ago with the discovery by Watson and Crick of the structure of DNA. In the really relatively short period of time since then there has been an enormous unfolding of new knowledge about our cells and our genes, as well as an explosion of new instruments and technologies. This has permitted an understanding of the functioning of the human body in a way that we wouldn't have dreamed of 30 years ago.

Scientific discoveries form a chain reaction as each new finding builds on a previous one. Those of us who have followed this step-by-step development in the field of biomedical research have really been amazed by the rapidity with which new facts have accumulated.

And yet, as each one of my colleagues has indicated previously, we also know that we are still only on the threshold of a full understanding of the ways to totally prevent, diagnose, and treat the diseases which we heard about this morning.

It was in the early 1970's that researchers supported by NIGMS developed a new set of methodologies now known as recombinant DNA technology, about which all of us have been talking this morning. Aided by this technology many important new research tools have been developed.

### GENE MAPPING

One of the most important is gene mapping. It is now possible to locate particular genes, not only on specific chromosomes, but, indeed, on specific parts of those chromosomes.

This technology, as Dr. Bick told you earlier, recently was used in successful collaborative efforts between grantees of the NINCDS and the NIGMS to isolate, more rapidly than anyone thought would be possible, a marker on human chromosome 4 for Huntington's disease, the disease which, as you know, took the life of Woody Guthrie.

For the first time we have a real clue as to the cause of this devastating neurological disease. But, of greater importance is the fact that this gene mapping technique can be used as a model for studies of a number of other poorly understood genetic diseases—cystic fibrosis, for example.

### RESEARCH TRAINING

Mr. Chairman, as you know, the NIGMS has a special role in the training of the Nation's future generations of scientists. I am pleased to say that a recent study by the National Academy of Sciences has shown that Ph.D. recipients trained on NIGMS support are appreciably more likely to apply for, and to compete successfully for, research grants from NIH than are those Ph.D. recipients who were not supported on NIH training grants.

Interestingly enough, a very large number of these former NIGMS trainees obtain research grant support from the other NIH institutes. This shows the critical role that NIGMS has played and will continue to play, in all areas of biomedical research.

It is enormously important to continue to pursue the many promising research leads now available in order to maintain the exciting momentum of discovery that we have all talked about this morning and to continue to play a role in the critical research training programs that I have described.

### PREPARED STATEMENT

Senator WEICKER. Thank you. Your statement will be inserted in the record at this point.

[The statement follows:]

## STATEMENT OF DR. RUTH KIRSCHSTEIN

I am pleased to present to you once again the programs of the National Institute of General Medical Sciences (NIGMS). The particular mission of this Institute is to support the kind of basic research which is so fundamental that it serves as a foundation for the missions of all the other Institutes. Our role is to foster the development of new knowledge, concepts and methodologies that are needed to make progress in the disease-targeted studies supported by other components of the National Institutes of Health (NIH).

In an era when biomedical knowledge is expanding rapidly, the Institute is funding the research of an impressive number of scientists at the very forefront of their fields. Over one-half of the NIH-supported Nobel Prize-winning scientists have received grants from NIGMS. This impressive record continued this year, when a long-time NIGMS grantee, Dr. Henry Taube of Stanford University, won the Nobel Prize in chemistry for his work on the role of metals in electron transfer between biochemical compounds, an essential cellular function. Another grantee, Dr. Eric R. Kandel of Columbia University, received the prestigious Albert Lasker Basic Medical Research Award for his studies of the cellular mechanisms of learning.

Over two-thirds of the NIGMS research budget is allocated to studies designed to unravel the mysteries of the cell--the fundamental unit of life--and the hereditary material it contains. This emphasis reflects the fact that this miniature world holds the key to the major health problems of today, including cancer, atherosclerosis, genetic diseases, diabetes, and mental illness.

### Cellular and Molecular Basis of Disease

Recent studies have led to an explosive growth in the field of modern cell biology. Through an ingenious combination of electron microscopy, biochemical separations and analyses of cell parts, X-ray crystallography, and other biophysical techniques, researchers have shown the cell to be enormously complex and tightly organized. Each cell has its own power plants, its own digestive system, its own factories for making proteins and other essential molecules. Most important, each cell has an intricate chemical communications network through which it can regulate its own activities, as well as receive messages from other cells, send out messages of its own, and sense changes in its environment.

Although the cell is no longer uncharted territory and its fundamental features have been mapped and analyzed, cell biologists are still very far from understanding the mechanisms that control all of the cell's varied activities. They do not know, for example, what regulates the series of orderly changes involved in normal cell growth and development. It is one of the greatest mysteries in biology that, although each human being starts life as a single cell, which then divides into two identical cells that repeatedly divide, these cells differentiate, so that some develop into an eye, some make hair, some make bone or blood, and others become nerves or skin. How do the many different types of cells know what to do? Why do certain kinds of cells die, never to be replaced, while others go on reproducing? What happens to our cells as we age? Studies are underway to answer these most fundamental questions, since an understanding of the normal functioning of cells is the key to understanding disease.

Several grantees, most notably Dr. Gary Borisy of the University of Wisconsin, have been studying the control of intracellular structures called microtubules. These rigid rods, too small to see in the ordinary light microscope, play a vital role in cell movement, chromosome movement and cell division, as well as many other cellular functions. By assembling and disassembling microtubules within the cell and in the test tube, and by carefully observing their activity, scientists are beginning to understand the control and dynamics of cell movement, so necessary for the normal development of the embryo.

### Pharmacological Sciences

Surrounding a cell's internal structure is a membrane which does much more than simply act as a barrier. Activities inside the cell can be turned on or off as a result of signals received through this cell membrane via structures known as receptors. NIGMS grantees are actively studying membranes and receptors, since improper functioning of either is linked to a variety of illnesses such as diabetes, and since the action of most chemicals, including drugs, begins at the cell membrane.

One grantee, Dr. Henry R. Bourne of the University of California, San Francisco, has developed a series of mouse cell lines having defects in one or more of the components necessary for intracellular response to the binding of a hormone to its receptor. He has found that the defect present in one of these cell lines--the absence of a protein that initiates the cell's response to an external stimulus--is the same as the defect in cells from patients with a hereditary endocrine disorder leading to a severe decrease in blood calcium. This is a clear example of a direct link between a receptor disorder and a specific disease, and it points the way to possible therapeutic interventions for this and many other genetic diseases.

## Genetics

The past 30 years have seen tremendous advances in the field of genetics. A new era began in 1953, when Drs. James Watson and Francis Crick described the structure of DNA, the "master molecule" of heredity. By 1966, the problem of how DNA codes for the correct amino acids to build a particular protein was solved. It began to look as if DNA would yield its secrets in a fairly straightforward way. Indeed, at the end of the 1960's, scientists generally believed that DNA was a static molecule, that the sequence of chemicals on that molecule represented a direct code for making protein and that, although mutations could occur, the genetic material was basically stable.

In the early 1970's researchers, many working with NIGMS support, developed a new set of methodologies known as recombinant DNA technology. This technology is based on the ability to cut segments of DNA at specific sites, to combine these segments with other DNA, and to manipulate the new hybrid molecule for basic or applied research purposes.

Aided by this new technology, scientists are now making startling discoveries about genetic material:

- Transposable elements, or "jumping genes"--segments of DNA that move within or between chromosomes--have been shown to be important factors in producing genetic changes. Originally identified by 1983 Nobel Prize winner, Dr. Barbara McClintock, "jumping genes" are now under intense study by a large number of NIGMS grantees who believe that they may play a role in such diverse processes as normal development, cancer and the immune response.
- Intervening sequences--stretches of genetic material that are not known to code for the synthesis of gene products--have been found to interrupt

the coding sequences of active genes, a phenomenon which seems to be important in development as well as in evolution.

° Ribonucleic acid (RNA) can act as a catalyst. Although it has been known for some time that genes (DNA) are transcribed into RNA which, in turn, specifically directs the synthesis of vital proteins, two recent discoveries by NIGMS grantees reveal that some RNAs can function as enzymes. Enzymes are biological catalysts, or substances that speed up biological reactions. Until recently all enzymes were thought to be proteins. The finding that RNA can also catalyze such reactions may profoundly affect our understanding of basic biochemistry, and indicates that much more remains to be learned about the nucleic acids, DNA and RNA.

Another remarkable advance is the development of gene mapping, a powerful research tool which, by isolating and identifying particular markers on a chromosome, makes it possible to locate certain other genes, not only on particular chromosomes, but, in some cases, on specific parts of those chromosomes. Last fall, grantees of NIGMS and the National Institute of Neurological and Communicative Disorders and Stroke isolated a "marker" on human chromosome number 4 which has been shown to have a close association with the gene for Huntington's Disease. This is an extremely important advance in efforts to combat this devastating neurological disease. But perhaps equally important is the discovery that gene mapping and other techniques of basic molecular biology can be used to study a genetic disorder whose biochemistry is completely unknown and for which there are no known cellular markers. This approach may be used as a model for work on other genetic diseases, such as cystic fibrosis, a common but as yet unexplained disorder.

## Burn and Trauma Research

Over 10,000 Americans die each year from severe burns, many of them children and the elderly. The major problem facing scientists in the field of trauma and burn research is the absence of an adequate understanding of the mechanisms that underlie the complications of serious injury, including burns. To this end, NIGMS grantees are studying the basic cellular, molecular, biochemical, and physiologic changes that occur as a result of severe trauma.

Dr. Thomas Hunt of the University of California, San Francisco, is studying agents that can promote the rate of wound healing by stimulating the growth of platelets, skin cells, and connective tissue. He and his colleagues have isolated a substance known as "angiogenesis factor" in the fluid from wounds in rabbits. This factor is a powerful stimulant for the growth of blood vessels and thus is very important in wound healing. Dr. Hunt has found that extracts of human wound fluid also stimulate blood vessels to grow in rabbit tissue. Human angiogenesis factor, if purified or synthesized, could be a very useful treatment, especially for wounds that are difficult to heal.

## Research Instrumentation

NIGMS supports a number of scientists who are developing or improving important instruments used in biomedical research. A prime example is nuclear magnetic resonance (NMR), which was originally developed as a research tool but which recently has been applied to clinical problems. This non-invasive technique is now being directed toward studies of intact tissues and organs, and is already providing valuable insights into energy metabolism.

Grantees of this Institute are also combining computers with microscopes in order to view cell components in greater detail, reconstruct their images in three dimensions, and relate structure more closely to function.

## Research Training

NIGMS funds two-thirds of all predoctoral trainees supported by NIH, as well as a sizeable number of postdoctoral fellows. A recent study by the National Academy of Sciences has shown that Ph.D. recipients who were trained with NIGMS support are appreciably more likely to compete successfully for NIH research grants than are Ph.D. recipients who have had no NIH predoctoral support. Interestingly, a large number of these former NIGMS trainees obtain research grant support from other NIH Institutes. This demonstrates the critical role that NIGMS has played--and continues to play--in training researchers for all areas of biomedical endeavor.

The Institute's unique role in research training includes its stewardship of two programs addressing special needs. For 20 years, NIGMS has supported the Medical Scientist Training Program (MSTP) to provide scientific and medical training leading to the combined M.D.-Ph.D. degree for highly motivated students with outstanding research and academic potential. An evaluation of the MSTP program has shown that about 70 percent of those who received the combined degree 5 or more years ago are now involved in academic pursuits.

## Minority Access to Research Careers

The other special NIGMS training program, the Minority Access to Research Careers (MARC) Program, seeks to increase the numbers and the capabilities of minority scientists engaged in biomedical research and to strengthen scientific curricula and research opportunities at institutions with substantial minority enrollments.

The MARC Program has created a new awareness of the exciting career opportunities in biomedical research among minority students. A high percentage of MARC undergraduate trainees are entering graduate schools, where their presence is providing an increased number of role models for younger minority students. Another noteworthy effect of the program has been a significant increase in the number of science majors at those minority institutions holding MARC awards.

Mr. Chairman, to pursue the many promising research leads and continue the critical research training programs that I have described, the budget request for the National Institute of General Medical Sciences for Fiscal Year 1985 is $423,853,000, an increase of $8,219,000 over the comparable Fiscal Year 1984 level. I would be pleased to answer any questions you might have or to provide any additional information you may request.

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## Biography of Dr. Ruth Kirschstein

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|---|---|
| POSITION: | Director, National Institute of General Medical Sciences |
| BIRTHPLACE and DATE: | Brooklyn, New York<br>October 12, 1926 |
| EDUCATION: | A.B., magna cum laude, Long Island University, 1947<br>M.D., Tulane University School of Medicine, 1951 |
| EXPERIENCE: | Director, National Institute of General Medical Sciences, September 1974-present<br>Deputy Associate Commissioner for Science, FDA, 1973-1974<br>Acting Deputy Director, Bureau of Biologics, FDA, 1972-1973<br>Assistant Director, Division of Biologics Standards, NIH, 1971-1972<br>Chief, Laboratory of Pathology, DBS, NIH, 1965-1972<br>Acting Chief, Laboratory of Pathology, DBS, NIH, 1964-1965<br>Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH, 1962-1964<br>Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH, 1960-1962<br>Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH, 1957-1960<br>Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH, 1956-1957<br>Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine, 1954-1955 |

Resident, Pathology, Providence Hospital, Detroit, Mich., 1952-1954
Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, Ga., 1952
Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y., 1951-1952

CERTIFICATION: Medical Specialty Board Certification, Pathology (anatomic and clinical pathology), 1957

ASSOCIATION MEMBERSHIPS:
American Association of Immunologists
American Association of Pathologists
American Society of Microbiology

SPECIAL AWARDS or CITATIONS:
Institute of Medicine, National Academy of Sciences, 1982
Presidential Meritorious Executive Rank Award, 1980
PHS Superior Service Award, 1978
DHEW Superior Service Award, 1971

COMMITTEE MEMBERSHIPS:
Invited member of World Health Organization Expert Group on International Requirements for Biological Substances, Geneva, Switzerland, 1965 and 1971
Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral. Geneva, Switzerland, 1967
Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975
Member, National Commission on Diabetes, 1975
Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975
Member, Ad Hoc Committee on Reserpine and Breast Cancer, 1974-1977
Chairperson, NIH Grants Peer Review Study Team, 1975-1976
Member, Editorial Board, Journal of Toxicology and Environmental Health, 1973-1977
Member, Fogarty International Center Scholars-in-Residence Advisory Committee, 1977-1982
Member, NIH Coordinating Committee on Manpower, 1978-present
Chairperson, PHS Task Force on Women's Health Issues, 1983-present

## BUDGET IMPACT

Senator WEICKER. Where does the President's budget impact most harshly on your Institute?

Dr. KIRSCHSTEIN. Mr. Chairman, if I had to pick the one area where we are impacted most it would be in the area of support of individual investigator-initiated research grants. What I have described to you is just one small fraction of all the high quality research activity now going on in the fields of molecular biology, genetics, pharmacology, biochemistry, chemistry, and cellular and molecular biology—much of which, although excellent science, will unfortunately not be supported under this budget.

There is one other area, if I were to add a second one, and that is that the Institute is, as I said, unique in that we provide the predominant support at NIH for predoctoral, pre-Ph.D. trainees that are the Nation's future scientists. These are the individuals who will be making the progress that you heard about in industry-oriented problems in the future.

Senator WEICKER. And yet the budget justification shows that as far as your Institute is concerned, your competing grants are actually going up?

Dr. KIRSCHSTEIN. Yes; in fact they are going up by a small number, Mr. Chairman, approximately 23, as I recall. My concern is that we are receiving a very large number of superb grant applications in basic research which we are unable to support. So, despite the fact that the number we can award is going up a bit, a number of excellent grants fall beyond our priority score cutoff of 160. Along with NIAID, NIGMS has the lowest priority score cutoff of any institute.

Senator WEICKER. I suppose the reason that I am surprised that you mentioned the competing grants in your instance is that as far as your training program is concerned it has been going downhill at a very rapid rate. There were 3,700 trainees in fiscal 1983. It dropped 300, to 3,433 in the current year, and 3,200 in fiscal year 1985 requests.

Why aren't there more priority items?

Dr. KIRSCHSTEIN. They are both priority items. However, I think to take maximum advantage of the enormous advances in molecular biology today requires that there be a sustained level of support for investigator-initiated research. Unfortunately, right now we can only pay research grants at the very highest priorities. Since there is so much good research above that we may be sending a message of discouragement to the scientific community.

We also send such a message of discouragement when we cut the number of trainees, although the impact of that will not be felt immediately. It will be felt something like 8 to 10 years from now.

Senator WEICKER. What level of new grants would you like to have if you had your druthers?

Dr. KIRSCHSTEIN. In the ideal world, I would like to have the ability to pay at the award rate that Dr. Wyngaarden mentioned in his speech to the AAMC, namely about 45 to 50 percent of approved applications. That would be approximately 985 new and competing research project grants.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There will be other questions for response to the record.

I thank you very much, Doctor, for your testimony.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the Fiscal 1985 NIH budget--small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget--or were you simply handed a number and told to find ways to live within it?

Answer: Throughout much of the budget formulation process, the Institute was consulted both about its request and about a number of options which various levels of budget review wished to consider. For this fiscal year's budget, as has happened in past years, the Office of Management and Budget made decisions on behalf of the President which established the overall funding level for the National Institutes of Health, as well as the funding targets for research grants and trainees. Within these parameters, the National Institute of General Medical Sciences developed the President's Fiscal Year 1985 budget.

Question: What is the impact of the budget request on your Institute and what will it do to the scientific momentum you are trying to maintain?

Answer: Under the Fiscal Year 1985 budget, the NIGMS will continue to emphasize support both of the most meritorious research project grant applications it receives and of high quality training of future research scientists. We estimate that the Fiscal Year 1985 budget will permit us to fund 2,683 research grants and 3,202 trainees, 56 fewer grants and 231 fewer trainees than provided for in the Institute's 1984 budget. Although this budget will allow all trainees to be given a 5 percent stipend increase, the reductions from the Fiscal Year 1984 levels will mean that a number of excellent research projects, primarily in the fields of genetics, cellular and molecular biology, and biophysics, will not be funded and that efforts to train a talented cadre of future research scientists will be curtailed. There are, however, always more initiatives worthy of funding than there are resources.

Question: To what extent will your new and continuation grants be funded below full cost levels--and what important research will be delayed or eliminated as a result?

Answer: In Fiscal Year 1985, new and competing grants will be funded at an average of 8% below full costs, while noncompeting continuation grants will be funded at an average of 4% below full costs. These downward negotiations in grant budgets will mean that research investigators in all the Institute's program areas will have to curtail the level of effort on their projects, raising the likelihood that their progress will be slowed. Some investigators may defer procuring new equipment intended to speed-up their work; others might cut back on the time devoted by technicians to the project; and still others might reduce the number of experimental procedures which their projects had proposed to accomplish during the period. These downward negotiations, however, are not expected to affect research to an undue degree.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84? What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: Funding of NIGMS-supported centers will remain essentially stable under the Fiscal Year 1985 budget. Just as in Fiscal Year 1984, the NIGMS will support 17 centers, limited to those scientific areas for which we believe increased collaboration between basic scientists and clinicians is necessary to enhance the research effort. Because the individual investigator-initiated research project grant is the most appropriate mechanism for supporting the fundamental, untargeted research which is at the heart of the NIGMS mission, the Institute has focused its support for centers in only a few areas--pharmacological sciences, anesthesiology, trauma and burn, genetics, and molecular pathology. The Fiscal Year 1985 budget for these research centers will, we believe, permit us to maintain an appropriate level of support in these areas for the translation of the results of basic research into prevention and treatment.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: The Fiscal Year 1985 budget for research training for NIGMS is $48,446,000 to support an estimated 3,202 trainees. This represents a reduction of $354,000 and 231 trainees from the Fiscal Year 1984 level. The impact of this lower level of support for research training is likely to be felt across all fields of biomedical science some five to ten years in the future when fewer research scientists emerge from the high quality, multidisciplinary training programs or individual fellowship experiences funded by NIGMS.

Question: How much additional funding above the budget would be required in Fiscal 1985 to maintain your Institute at the same level of effort as in Fiscal 1984?

Answer: An additional $15,204,000 over the President's Fiscal Year 1985 budget would be required to maintain the current, Fiscal Year 1984 level of effort for all NIGMS programs.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction--and where will you take it? With what effect on research?

Answer: The NIGMS share of the proposed staff reductions at NIH is 7 positions. The Institute plans to accomplish these personnel savings largely through attrition. Thus, staff turnover will determine in which areas of extramural grants administration and Institute management the reductions will occur. The Institute will make every effort to ensure that the personnel who constitute the Institute's remaining 164 full-time equivalents continue to serve as careful and skilled stewards of the Institute's research grant programs.

## RESEARCH TRAINING

Question: Your training program seems to be going down hill, at least in numbers. You were at 3,700 trainees in Fiscal 1983, dropped to 3,433 in the current year and your FY 1985 request is for 3,202.

What's the impact of a reduction of the training effort both on the Nation's ability to do research and on our stature in the field of training biomedical researchers?

Answer: It is likely that the impact of this reduction in trainees will be felt in five to ten years when there could be fewer new scientists, trained with Federal resources, to embark on research careers. Because trainees and fellows trained with past NIGMS support have been significantly more successful in competing for research grant support from NIH, the current and proposed reductions in trainees may result in a diminished infusion of creative new research ideas into the research milieu in future years. Nevertheless, the Fiscal Year 1985 budget does provide support for 2,860 predoctoral trainees and fellows and 342 postdoctoral fellows and trainees, including 700 Medical-Scientist Program trainees and 385 Minority Access to Research Careers Program trainees and fellows. All of these trainees and fellows will be of the very highest caliber.

Question: Your training request for Fiscal 1985 is for $48 million and 3,202 slots. What was your original request to NIH, the Department and/or to OMB?

Answer: The table below presents the NIGMS requests for research training which were submitted at successive levels of review during the budget formulation process.

| | Training Slots | Amount (in Millions) |
|---|---|---|
| Request to NIH.................. | 4,050 | $66.4 |
| Request to DHHS................. | 3,225 | $47.8 * |
| Request to OMB.................. | 3,202 | $48.4 * |

*In the period of time between these two requests, the cost of tuition as estimated from pending training grant applications was raised so that the projected total cost per trainee slot increased.

Question: In your professional judgment, how many people should you be training in the new fiscal year?

Answer: The Committee on National Needs for Biomedical and Behavioral Research Personnel of the National Academy of Sciences is mandated by the Congress to determine the Nation's research personnel needs. In its latest report, issued in 1983, the Committee has recommended that a total of 12,495 trainees in the fields of biomedical and behavioral research be supported during Fiscal Year 1985. Of these, we estimate that approximately 10,500 trainees would be supported by NIH programs, and that the NIGMS share would be about 3,800. In my professional judgment, these numbers would provide the appropriate cadre of future biomedical researchers.

Question: I'm sure you are proud of the people you train, but do they do any better than those not trained at NIH in terms of getting research dollars?

Answer: Recently, the National Academy of Sciences (NAS) conducted a follow-up study of the research careers of predoctoral trainees and fellows supported by the NIGMS between 1967 and 1980. The study results show that former NIGMS trainees not only are 50%

more likely to apply for NIH research grant support, but also are 100% more likely to obtain such support than are investigators whose training was not supported by NIH. These findings, along with others pointing to the fact that more trainees supported by NIGMS pursue both postdoctoral training and later research careers, confirm that NIGMS-supported training programs indeed pay off in preparing the very finest scientists for future research endeavors.

## NIGMS MISSION

Question: General Medical isn't the glamour institute and you don't read about it every day in the newspaper. But its mission is as important as any out at NIH. Your mission is really basic research--genetics, for example--and training of future researchers. What scientific advances have you achieved over the last year and what do you look for in FY 1985?

Answer: While NIGMS is seldom mentioned in the lay press by name, the important research findings developed by our grantees are being noticed with greater and greater frequency by the media because of the new frontiers they are opening up in the fight against disease. This has been particularly true in the area of genetics research, where the recombinant DNA techniques developed by NIGMS grantees are beginning to make possible improved methods of both diagnosis and treatment for a host of disorders.

Important scientific advances achieved over the past year with NIGMS support include the following:

- Down Syndrome: Researchers at the University of California, San Francisco (Dr. Charles J. Epstein and colleagues) have made major progress in the development of an animal model for Down Syndrome, a genetic disorder which is the leading cause of mental retardation and congenital heart defects in the United States. Having observed important similarities between the developmental defects in human fetuses with Down Syndrome (characterized by three instead of the normal two chromosomes #21) and mouse fetuses with three chromosomes #16, these investigators have been working hard to find ways to develop a strain of mice which could be studied to determine the precise mechanisms by which an extra chromosome leads to developmental errors. Within the past year, they have partially overcome a major problem in this regard, the fact that very few mice with three chromosomes #16 manage to survive after birth.

- Development of Anti-Cancer Drugs: While studying the function of a class of enzymes known as the topoisomerases (the enzymes that are responsible for the winding and unwinding of DNA), Dr. Leroy Liu and his associates at Johns Hopkins University discovered a relationship between these enzymes and the way in which certain anti-cancer drugs work; i.e. the drugs cause cell death by interfering with the activity of a specific form of topoisomerase, called Topoisomerase II. This has opened up the intriguing possibility that, in the future, anti-cancer drugs could be developed which only interfere with Topoisomerase II in cancerous cells. Such drugs might not cause the serious side effects caused by currently-used chemotherapeutic agents.

- Drug Metabolism: The cytochrome P-450 system represents a naturally occurring complex of enzymes which are produced by specific genes in response to the presence of foreign substances, including potentially toxic drugs. These enzymes help the body to eliminate these substances, or to turn them into less harmful forms. Researchers working with NIGMS support (Dr. Milton Adesnik and his colleagues at the New York University Medical Center) have recently made significant progress in determining the structure of cytochrome P-450 genes, as well as learning how they are turned on and off. Their findings could help lead to the future development of ways to improve drug therapies, while also decreasing toxic side effects.

- DNA-Protein Binding: DNA, well-known as the basic genetic material, could not perform any of its many essential functions alone. Rather, DNA acts in concert with hundreds of different proteins which bind, cut, repair, replicate, transcribe or change the DNA as required by the cell involved. Research on DNA-protein complexes is therefore of major importance to understanding many naturally occurring biological processes, as well as a number of genetic disorders caused by defects in specific DNA-binding enzymes. An NIGMS grantee at the University of Pittsburgh (Dr. John M. Rosenberg) has recently reported a major breakthrough in this area--the first visualization of a DNA-protein complex by X-ray diffraction methods. This work is expected to help pave the way for studies of other complexes and to help provide a greater understanding of protein-DNA interactions in general, a necessary first step to understanding how defects in enzymes can cause problems in basic cellular and genetic processes.

- Huntington's Disease: Within the past year, an NIGMS grantee (Dr. Michael Conneally at the University of Indiana), using cell lines maintained by an NIGMS contractor, played a key role in identifying the chromosomal site of a genetic marker closely associated with the gene for Huntington's Disease. This discovery is expected to make possible the improved detection of presymptomatic carriers of this late onset neurodegenerative disease, and may eventually lead to a dramatic decrease in its incidence.

For FY 1985 and beyond, the following research areas are considered to offer the most important scientific opportunities:

- Gene Mapping: The NIGMS has invested heavily in efforts to "map" human chromosomes, supporting the work of many teams of researchers who are performing the painstaking studies needed to identify the specific chromosomal sites of genes responsible for particular traits and genetic disorders. Work in this area is regarded as an important step toward eventually curing or preventing many genetic defects.

- Gene Therapy: NIGMS grantees have successfully corrected, in the laboratory, a genetic defect responsible for a severe human brain disorder by infecting human brain cells with a virus that inserts the needed gene into them, thereby restoring normal brain cell function. While it will be at least five years before the techniques involved can be tried on patients, it is believed that the new methods developed as part of this research will eventually lead to effective treatments for a wide variety of human genetic diseases, most especially blood disorders and immune deficiency diseases.

° Cell Receptor Studies: Research supported by the NIGMS on the structure and function of "receptors" embedded in the membranes of cells has already yielded great insights into both how cellular functions are regulated and how a number of diseases originate. Because the function of some of these receptors has been found to be critical to the way in which drugs act within the body, research in this area is especially important to efforts to develop new, more effective therapeutic agents.

° Enzymology: The NIGMS is supporting a number of studies which focus on gaining an understanding of the structure and function of enzymes, naturally occurring substances in the body which help to speed up (catalyze) the rate of normal biochemical reactions within the body. One goal is to be able to artificially produce enzymes capable of stimulating the manufacture of desired biochemical products. Another is to learn how to inhibit enzyme activity under certain circumstances. Several pharmaceutical firms have used enzyme inhibiting mechanisms in the design of new antihypertensive medications, for example.

° Biophysics: One of the most important areas of basic research today is biophysics, as illustrated by the recent awarding of the Nobel Prize in Chemistry to Dr. Henry Taube, an NIGMS grantee, for his work on the role of metals in biology. The continued development of Nuclear Magnetic Resonance (NMR) spectroscopy and imaging, together with recent findings arising from studies of protein-nucleic acid interactions, have made this a particularly exciting field of study.

## ROLLER COASTER FUNDING

Question: The Subcommittee notes that you're on something of a roller coaster as far as new research grants are concerned. You had 835 in 1983, 721 in 1984 and your request for 1985 is 744. What does this do to your ability to keep research scientists interested in your programs?

Answer: The "roller coaster" phenomenon to which you refer is, of course, one of our concerns. It is reflected not only in the number of new and competing research grants the Institute is able to fund each year, but the total number of grants as well (2,655, 2,739, and 2,683 awards in the last three years). These up and down swings may, we fear, tend to discourage investigators in the basic research fields supported by the Institute, but beyond this is the effect they may be having on the bright, young people considering careers in research. These young people are clearly aware of the impact which a lack of stable funding has on the science faculty who represent their role models, and this could have an impact on their own career choices.

BURN RESEARCH

Question: We know that you are supporting some interesting work in the field of burn research and we want to keep abreast of developments. What sort of success are researchers having in using epidermal cells in treating burn wounds?

Answer: Scientists supported by the NIGMS are investigating various approaches to using epidermal cells in materials to cover burn wounds. One team of investigators is exploring the suitability of coating the artificial "dermal" skin, already developed and tested by other NIGMS scientists, with cells derived from a culture grown from a very small patch of the patient's own epidermal cells. They are perfecting techniques which will encourage the rapid proliferation in culture of these epidermal cells and permit their successful integration with the artificial skin. These scientists believe that this "living" artificial skin, composed of the patient's own epidermal cells and a synthetic, biodegradable substrate, will have the advantages of minimizing the risk of rejection and substantially reducing the time required for covering burn wounds.

Another team of research scientists is trying to develop and test an "epidermal skin" equivalent. By separating human epidermal cells from cadaver skin and growing them in a sterile culture, these scientists have been able to produce a multilayered epidermal membrane which has been successfully used as a partial-thickness graft on skin wounds in both animals and humans. This epidermal membrane has not been rejected, as other "foreign" grafts are, making grafting of the patient's own skin unnecessary, and minimizing scarring. While both of these techniques for using epidermal cells seem promising, further refinements and research must proceed before either can be used routinely to treat burn patients.

Question: We understand that researchers you funded at MIT and the Massachusetts General Hospital have been working on development of artificial skin. Any significant results to report?

Answer: Research on artificial skin continues to show promise and to move toward clinical application. As we reported last year, the artificial skin first developed by Dr. Ioannis Yannas of the Massachusetts Institute of Technology and Dr. John Burke of the Massachusetts General Hospital has been used successfully in clinical trials on 40 severely burned patients. A commercial laboratory is developing this "Stage I" artificial skin and has received FDA approval to test its efficacy in four burn centers--the University of Washington, Seattle; the University of Iowa; the Washington Hospital Center in Washington, D.C.; and the Massachusetts General Hospital and Shriners Burns Institute in Boston. Successful trials of this "Stage I" artificial skin should mean that, within a year or so, it will be widely available for treating burn patients. Meanwhile Drs. Yannas and Burke are continuing to develop a "Stage II" artificial skin in an effort to reduce the time required for skin closure, to avoid the need for subsequent skin grafts, and to reduce contractures and scarring. This "Stage II" material differs from "Stage I" artificial skin in that it is seeded with a small number of the recipient's own skin cells which grow to cover the wound with new skin, making subsequent skin grafts unnecessary. Trials in animals of this improved material are continuing and are aimed at refining the composition of, and techniques associated with, the "Stage II" artificial skin. Trials of the improved materials in human burn patients may soon be possible.

## QUESTION SUBMITTED BY SENATOR WILLIAM PROXMIRE

### PBME PROGRAM BUDGET

Question: Dr. Kirschstein, despite the fact that the Congress increased the Fiscal Year 1984 budget request for your Institute, this year's justifications indicate that you will be allocating about $1.3 million less to physiology and biomedical engineering in 1984 than you estimated last year. Can you tell us why?

Answer: In the Fiscal Year 1984 column of the 1985 budget, the Physiology and Biomedical Engineering (PBME) Program budget total is $37.8 million. This apparent shortfall from the $39.7 million requested for this program in the FY 1984 President's Budget reflects the transfer of administrative responsibility for research and research training activities in anesthesiology from the PBME Program to the Institute's Pharmacological Sciences Program. This transfer follows from an organizational change, approved by the Director, NIH, designed both to reduce areas of scientific overlap and to stimulate the interchange of ideas among scientists in anesthesiology and pharmacology who are working in essentially related areas.

### SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow, April 4, when we will meet again in this room at 9 a.m. to conclude our hearing on the National Institutes of Health.

Tomorrow morning we will hear from the following—the National Institute of Child Health and Human Development, the National Eye Institute, the National Institute of Environmental Health Sciences, the National Institute on Aging, the Division of Research Resources, John E. Fogarty International Center, National Library of Medicine, and the Office of the Director and Buildings Facilities.

[Whereupon, at 11:55 a.m., Tuesday, April 3, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, April 4.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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WEDNESDAY, APRIL 4, 1984

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## NATIONAL INSTITUTES OF HEALTH

## NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

### STATEMENT OF DR. MORTIMER B. LIPSETT, DIRECTOR

**ACCOMPANIED BY:**

- **DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **JOEL R. HEDETNIEMI, EXECUTIVE OFFICER, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**
- **ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. The subcommittee will come to order to open our second day of hearings on the National Institutes of Health budget.

We shall hear first today from the National Institute of Child Health and Human Development.

The fiscal 1985 budget request for the Child Health Institute is $280 million, or about $5 million more than the fiscal 1984 level.

Here to tell us about this request is Dr. Mortimer Lipsett, Director of the Institute. Welcome, Dr. Lipsett, and you may proceed. Please introduce any of your colleagues you have with you, but first we will insert your statement.

[The statement follows:]

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## STATEMENT OF DR. MORTIMER B. LIPSETT

The National Institute of Child Health and Human Development (NICHD) has one of the broadest mandates of any of the Institutes of the National Institutes of Health (NIH). Its research encompasses the developmental continuum from fertilization to embryonic and fetal development, through infancy, childhood, adolescence, and the reproductive years.

To carry out its research mandate, the NICHD supports a combination of biomedical and behavioral research in child growth and development and in reproduction. Research in child growth and development covers subjects ranging from human embryology to growth and childhood learning and social development. Studies in reproduction encompass research beginning with the development of sperm and egg cells to studies of population and family dynamics. Much of this work is basic research, because the development of fundamental knowledge about reproductive biology, mechanisms of growth and early behavior is the key to preventing the biologic onset of disease or the emergence of behavioral problems.

### Contraception

Unwanted or unplanned pregnancy as well as pregnancy that is wanted but difficult to achieve can disrupt lives and marriages. Thus, the NICHD supports an active research program on both fertility regulation and on infertility.

Some 10 million U.S. men have had vasectomies and about 500,000 more undergo the operation each year. The Institute recently released the results from the most comprehensive assessment of the possible health consequences of vasectomy ever conducted. The study concluded that vasectomy is safe, that men who have had vasectomies are as healthy as other men and have suffered no adverse health effects.

A comprehensive study initiated during the 1970s on the relationship between oral contraceptives and the occurrence of breast, endometrial and ovarian cancer is now nearing completion. Preliminary results from this study provide considerable reassurance that oral contraceptives do not influence the occurrence of breast cancer, even among women with known risk factors for breast cancer. Also, the study has confirmed earlier reports that oral contraceptives decrease the risk of ovarian cancer.

The clinical trial of the disposable vaginal contraceptive sponge has been completed. The product has been approved by the Food and Drug Administration and is currently being marketed in the U.S.

### Infertility

NICHD scientists succeeded in simulating the hormonal environment of pregnancy in monkeys without functioning ovaries, thereby allowing them to carry a surrogate embryo to term and to deliver a healthy baby.

Other NICHD-supported researchers have used injection of a brain hormone, luteinizing hormone-releasing hormone (LHRH), to induce a single ovulation in women and sperm production in infertile men with subsequent successful childbearing.

## Birth Defects

Approximately 3 percent of infants have a malformation detected at birth and some 4 to 7 percent of all children are eventually diagnosed as having a congenital defect. Some of these defects are genetic; others are the result of some flaw in embryonic or fetal development. In basic studies on birth defects, NICHD scientists are studying the molecular processes involved in the transmission of genetic information from parent to child, and the expression of this information as the organism develops from a single cell into a complex individual. Because of the recombinant DNA techniques now available, it is now possible to examine how genes code for individual body parts, such as a limb or organ. It is likely that studies such as those being conducted in NICHD's own laboratories and by its grantees will lead to the discovery of "markers" for hereditary defects that can be used to diagnose and eventually to correct human abnormalities before birth.

NICHD researchers also are developing new techniques of gene transfer in which animal genes are cloned in bacteria and inserted into the eggs of mice; the eggs are fertilized in vitro and then transferred into surrogate mothers. These transferred genes are stably inherited through many generations. This new method will teach us how and why genes are turned off or on in different tissues and at different times. Moreover, the gene transfer technique could ultimately lead to cures for many genetic diseases.

An NICHD-grantee has succeeded in cloning the gene responsible for PKU, a serious inborn error of metabolism that causes severe mental retardation. This research advance will permit physicians to determine whether a fetus has PKU and to begin to explore gene replacement as a means of preventing PKU.

## Low Birthweight

Low birthweight (less than 5 1/2 pounds) continues to be the major public health problem in the U.S. in the area of maternal and child health. More than 200,000 LBW children are born in the U.S. each year. They account for almost three-fourths of the deaths during the first 28 days of life and two-thirds of all infant mortality. The cost of neonatal intensive care, which has been increasingly successful in keeping many of these babies alive, exceeds $2 billion a year.

Research leading to the prevention of low birthweight and premature delivery is a major priority of the NICHD.

A major step in prevention of prematurity will be understanding what triggers normal labor. NICHD grantees may have taken a major step toward this understanding when they recently succeeded in isolating a substance in the urine of unborn babies that might be the "trigger" researchers have long sought.

A new attack is being made on the preterm labor problem by a multi-center clinical trial conducted jointly by the NICHD and the

National Institute of Allergy and Infectious Diseases. This trial will seek to identify specific types of infection of the maternal genital and urinary tracts that may increase the risk of preterm birth. Then, by antibiotic treatment of such infections, an attempt will be made to reduce the preterm birth rate.

Currently, a major killer of premature infants is respiratory distress syndrome (RDS). The lungs of premature babies lack sufficient quantities of the natural lubricant, surfactant, that normal newborns have to keep the tiny air sacs in their lungs from collapsing and sticking together. A major advance in the treatment of RDS was made in 1983 when NICHD-supported researchers isolated surfactant from the amniotic fluid of healthy, full-term pregnant women undergoing cesearan childbirth. They dripped the purified substance into the windpipe of newborn babies with RDS and found that it significantly improved their breathing within minutes. Studies are under way to establish the long-term effectiveness and safety of using surfactant from amniotic fluid to treat RDS.

Low birthweight can be a consequence of intrauterine growth retardation as well as of premature delivery. Many cases of intrauterine growth retardation are not diagnosed before birth, impeding research and treatment efforts. NICHD researchers are working on improved diagnostic techniques and are making progress in treating it. Preliminary work in animal models has shown that injecting a mixture of glucose and amino acids into the amniotic fluid where it is ingested by the fetus can improve fetal growth and outcome.

## Sudden Infant Death Syndrome

The causes of Sudden Infant Death Syndrome (SIDS) continue to elude investigators. SIDS research is now at a cross roads. At a recent NICHD-sponsored workshop to map future research directions in SIDS, the participants agreed that a promising hypothesis to investigate is that SIDS results from a failure to integrate a number of regulatory systems in the brain. New tools are available in the neurosciences and neuropathology to study brain development, and the NICHD plans to apply these to SIDS research.

## Nutrition

The NICHD also supports studies on normal infant development, including nutritional needs. Research has established that human breast milk is the best food for infants, both normal newborns and sick or premature babies.

NICHD-supported researchers have developed a process to destroy the most common bacteria in human milk without affecting the milk's antibodies. The prime benefactors of this promising pasteurization technique will be the human milk banks that have been established in many U.S. hospitals and clinics where breast milk is stored and distributed to premature and hospitalized infants.

NICHD intramural scientists are looking at the mechanisms by which encapsulated bacteria cause disease in children. They have made progress in developing a vaccine against a specific type of organism that frequently causes meningitis and other diseases in infants. We are attempting to develop a safer and more effective vaccine against whooping cough (pertussis); researchers have improved methods to isolate the whooping cough toxin and inactivate it while preserving its ability to elicit immunity.

## Behavior and Mental Retardation

Early testing of a newborn's ability to see, hear, and feel is crucial to understanding the development of early learning and communication skills. An NICHD-grantee has developed a method --using a newborn's eye blink reflexes -- that makes it possible to test the hearing of 2-day old sleeping infants.

The explosion of research in the areas of infant psychology and learning has produced new techniques to identify retarded infants early. The advantage of early identification is that it has been demonstrated that early corrective intervention often prevents more serious mental handicaps from developing.

## Demographic and Behavioral Sciences

The NICHD also supports research in the demographic and behavioral sciences to study factors governing variations in the growth, distribution and characteristics of people and the impact of population changes on the health and well-being of individuals, families, and society as a whole.

NICHD-supported research is addressing the role of family factors on fertility related behavior among teens. This study shows that socioeconomic characteristics of the family are not associated with the teen's propensity to be sexually active. However, rates of sexual intercourse and pregnancy are significantly higher among teenagers whose parents are not currently married and among those with many brothers and sisters. Girls who report that their parents closely monitor their early dating behavior are less likely to be sexually active.

In addition to its research on adolescent pregnancy, the Institute also supports research on the consequences of family size on the social, psychological, and economic well-being of both parents and children. This includes studies on childlessness and delayed childbearing.

By supporting and conducting research to ensure that every pregnancy is a healthy and wanted one, to identify the causes of developmental and birth defects and understand the biological mechanisms involved, and to delineate the behavioral influences which act upon the developing child within the family and society, the National Institute of Child Health and Human Development is providing the research basis for producing a healthier population.

## Budget Request

Mr. Chairman, the National Institute of Child Health and Human Development requests $280,178,000 for Fiscal Year 1985, an increase of $5,005,000 over the 1984 level. I will be pleased to answer any questions you may have.

## BIOGRAPHY OF DR. MORTIMER B. LIPSETT

Present Address: 8 North Drive, Bethesda, Maryland - 20814

Birth: February 20, 1921, New York, N. Y.

Marital Status: Married - Two Children

### Education:

1943 - A.B., University of California
1947 - M.S., University of Southern California
1951 - M.D., University of Southern California
Certified: American Board of Internal Medicine, 1958
Recertified: 1974 and 1980

### Professional History:

| | |
|---|---|
| 1946 | Research Assistant, University of Southern California |
| 1947 | Research Associate, University of Southern California |
| 1951-1952 | Intern, Los Angeles County Hospital |
| 1952-1954 | Resident, Internal Medicine, Sawtelle Hospital, Veterans Administration, Los Angeles, California |
| 1953-1954 | Research Assistant, Cardiology, University of California |
| 1954-1956 | USPHS Fellow, Sloan-Kettering Institute, New York |
| 1956-1957 | Assistant Member, Sloan-Kettering Institute, New York |
| 1956-1957 | Assistant Attending Physician, Memorial Center, New York |
| 1956-1957 | Instructor in Medicine, Cornell University Medical College, New York |
| 1957-1959 | Medical Officer, Endocrinology Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD |
| 1957-1960 | Instructor in Medicine, Howard University School of Medicine, Washington, D.C. |
| 1959-1966 | Assistant Chief, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD |
| 1960- | Associate Clinical Professor in Medicine, Howard University School of Medicine, Washington, D.C. |
| 1960-1961 | Visiting Scientist, Karolinska Hospital, Stockholm, Sweden |
| 1963-1965 | Head, Endocrinology Service, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD |
| 1966-1970 | Chief, Endocrinology Branch, National Cancer Institute, NIH, Bethesda, MD |
| 1970-1974 | Associate Scientific Director (RB), Intramural Research, National Institute of Child Health & Human Development, NIH |
| 1970-1974 | Chief, Reproduction Research Branch, NICHD, NIH |
| 1974-1976 | Director, The Cancer Center Inc. for Northeast Ohio, Cleveland, Ohio |
| 1974-1976 | Professor of Medicine, Case Western Reserve University School of Medicine, Cleveland, Ohio |
| 1978- | Clinical Professor, Department of Medicine, Uniformed Services University of the Health Sciences, Dept. of Defense, Bethesda, MD |

| | |
|---|---|
| 1976-1982 | Director, Clinical Center, National Institutes of Health, Bethesda, MD |
| 1976-1982 | Associate Director for Clinical Care, NIH, Bethesda, MD |
| 1982-Present | Director, National Institute of Child Health and Human Development |

Professional Organizations:

American Association for the Advancement of Science
American Association for Cancer Research
American Federation for Clinical Research
American Physicians Fellowship, Inc., Board of Trustees - 1979
American Society for Andrology, Council - 1982
American Society for Clinical Investigation
Association of American Physicians
The Endocrine Society
  Chairman, Postgraduate Committee, 1973-1974
  Secretary-Treasurer, 1974-1978
  President, 1979
Harvey Society
International Society of Endocrinology
  Secretary General, 1976-
Society for Study of Reproduction

Committees and Boards:

| | |
|---|---|
| 1958-1960 | Member, Clinical Research Fellowship Review Panel, National Institutes of Health, Bethesda, MD |
| 1962-1965 | Co-Chairman, Clinical Research Committee, NIH, Bethesda, MD |
| 1963-1964 | Chairman, Endocrinology Committee, National Cancer Institute, NIH, Bethesda, MD |
| 1963-1965 | Member, National Institutes of Health Committee on Diagnosis and Treatment |
| 1963-1966 | Member, Specialty Fellowship Board of the National Cancer Institute, NIH, Bethesda, MD |
| 1963-1967 | Member, Committee on Therapy, American Cancer Society |
| 1964-1977 | Editor, Steroids |
| 1966-1968 | Member, Editorial Board, Journal of Clinical Endocrinology and Metabolism |
| 1966-1970 | Chairman, National Cancer Institute Breast Cancer Task Force |
| 1967-1970 | Member, Scientific Directorate, National Cancer Institute, NIH |
| 1968-1972 | Member, Reproductive Biology Study Section |
| 1968-1973 | Editor-in-Chief, Journal of Clinical Endocrinology and Metabolism |
| 1969-1976 | Member, American Board of Internal Medicine, Endocrinology Test Committee |
| 1970-1973 | American Cancer Society, Advisory Committee on Biochemical and Chemical Carcinogenesis |
| 1972-1974 | Chairman, Education Committee, NIH |
| 1972-1974 | Member, Technical Review Committee, Reproductive Biology, World Health Organization |
| 1973-1976 | Member, Veterans Administration Endocrinology & Metabolism Review Board |

| | |
|---|---|
| 1974-1976 | Member, Program Organizing Committee, Fifth International Congress of Endocrinology |
| 1974-1981 | Board of Editors, Cancer Research |
| 1975- | Endocrinology and Metabolism Committee, Food and Drug Administration<br>Member (1975-1977); Chairman (1978-1980); Consultant (1980- ) |
| 1979- | Member, Organizing Committee, International Steroid Congress |
| 1980- | Member, International Advisory Board, Technion-Israel Institute of Technology |
| 1981- | Member, Editorial Board, IRB |

Honors and Awards:

| | |
|---|---|
| 1950 | Alpha Omega Alpha |
| 1955 | Alfred P. Sloan Award for Cancer Research |
| 1959 | Diplomate, American Board of Internal Medicine |
| 1962 | Fellow, American College of Physicians |
| 1969 | Superior Service Honor Award, Department of Health, Education, and Welfare |
| 1973 | Corresponding Member, German Endocrine Society |
| 1976 | Distinguished Leadership Award of the Endocrine Society |
| 1980 | Senior Executive Performance Award |
| 1981 | DHHS Distinguished Service Award |
| 1982 | Senior Executive Service Meritorious Rank Award |
| 1984 | Distinguished Andrologist Award |
| 1984 | Transatlantic Lecturer; 3rd Joint Meeting of the British Endocrine Societies; Edinburgh, Scotland |

Listed In:

Who's Who in America
World Who's Who in Science
American Men and Women of Science

### SUMMARY STATEMENT

Dr. LIPSETT. May I introduce my Executive Officer, Mr. Hedetniemi.

Senator, the NICHD, in our opinion, deals with the future because the future is in our children. How they develop and mature, physically and behaviorally, will determine how they will perform as adults in our society. Efforts in this regard are a major part of the Institute's mission.

I would like to depart a bit from my statement and describe briefly three areas of emphasis for the Institute. They concern basic and clinical research leading directly to prevention.

First, we are proposing a broad initiative to reduce the incidence of low birthweight in infants. This is an important problem, as you know, because of not only its humanitarian and economic aspects, but because it is also a part of national pride.

A country's commitment to health and its success in maintaining the health of its citizens is judged in large measure by infant mortality. That is one of the criteria used around the world.

We still have about 50,000 births per year of infants weighing less than 3½ pounds. The significance of this is that those infants are susceptible to early death. They are at high risk for mental retardation, for cerebral palsy and for behavioral and cognitive disorders occurring later in life.

The bill for the country just for the time they spend in neonatal intensive care units is more than $2 billion a year. This doesn't tell us what the subsequent expense is over the lifetime of these infants.

In this low birthweight initiative, we have made plans for two additional centers concerned with fetal growth and with perinatal pharmacology. We are planning a network of neonatal intensive care units similar to some of the cancer treatment networks so that we can ask some more important questions and enlist the aid of all of these people together at any one time to give us answers more efficiently and more quickly.

We are going to expand research in areas directly related to fetal growth, the biologic prediction of fetal growth retardation, and the mechanism of premature labor.

It may be of interest, Senator, to you and the committee to know that those factors that some scientists have been identifying as important in fetal growth and development are very closely related to the genes that have a similar role in cancer. The two fields now are coming together, and the work of each amplifies the other.

Second, the leading causes of death among teenagers are accidents, suicides, and homicides. If we were to characterize accidents as sickness, we would say we were in the midst of an epidemic because of the high occurrence rate not only of death but of injury as well.

Now, it is here that studies of personality development, of risk-taking behavior, behavioral modification, and a host of still unidentified problems in human behavior need to be expanded.

Basic studies in the behavioral sciences are increasingly important to help us develop and devise strategies to improve the performance of children with mental retardation and to identify early in life those children who will need help because of more subtle changes. And this work is proceeding very well, I must say.

The studies in human behavior are necessary in still another area, teenage pregnancy. We need to know why girls become pregnant in their teens, and we need to know why young mothers don't take adequate advantage of prenatal care. All of this is a subject for the behavioral sciences.

The roles of family structure and individual personality patterns are also important, and they are under active investigation. The Institute is, therefore, aware of its major responsibility in human learning and behavior and will continue to make further progress in this area.

Third, the field of contraception remains a worldwide problem and still requires research even in the United States.

We still don't have an adequate choice of very effective and very safe contraceptives. We are making progress in developing some of the brain peptides that have been shown to suppress ovulation in women and spermatogenesis in men, and limited clinical trials are now being developed using these agents.

One other part of this program in contraception is the continuing evaluation of current contraceptives because the formulations do change over time, raising new questions.

This year the Institute reported the results of three rather extensive evaluation studies. I am happy to say that it turns out that vasectomy is, in fact, a safe procedure and that men who have undergone vasectomies show no long-term adverse side effects of any sort, and the incidence of coronary artery disease was the same as in a control population.

Oral contraceptives have been shown to decrease the incidence of ovarian cancer and of uterine cancer and not to affect, as far as we can tell, the incidence of breast cancer.

So there is encouraging news from the area of contraception instead of the usual dismal picture of a new risk being identified.

These are the three areas I wanted to highlight for you, and I am happy to answer any questions you may have.

Senator WEICKER. Let's talk about two of the matters you raise—infant mortality. What is the present rate in the United States per 1,000?

Dr. LIPSETT. The present rate per 1,000 is 11.

Senator WEICKER. Where does that place us among developed countries?

Dr. LIPSETT. The United States ranks 13th in the world.

Senator WEICKER. What is that rate in the major metropolitan areas?

Dr. LIPSETT. Well, in the major metropolitan areas it is actually somewhat higher because of the increased number of very low birthweight infants that come from the areas where there is lower socioeconomic status, where the attention to prenatal care is poorer, and the women who have these babies are younger.

Senator WEICKER. The attention to prenatal care is poorer? Is it not also so in the last several years that the availability of prenatal care is scarcer?

Dr. LIPSETT. I can't speak to that, Senator.

Senator WEICKER. Well, it is certainly a matter of the Federal Government's role in this area. It has markedly increased.

Dr. LIPSETT. Well, there is one thing that has been shown, and that is that the number of women who are seeking and using and getting prenatal care has increased.

Senator WEICKER. I had testimony last year in the public segment of these hearings from the health directors of two of the major cities in America that indicated that the problem with infant mortality in their jurisdiction was that the doctors in the hospital would be seeing these women for the first time as they literally were coming in, in labor without any prenatal care.

Dr. LIPSETT. There is no question that that happens. It is happening less often because I think that there have been a number of efforts made in many cities to acquaint the women with the advantages of prenatal care. There are data developed by our epidemiology staff which show the women are coming in for prenatal care.

Senator WEICKER. And I have got to confess, I consider being No. 12 or 13 among the developed nations of the world—I think that is a pretty poor statistic.

Dr. LIPSETT. It is a poor statistic.

Senator WEICKER. Especially for a Nation such as ours that in terms of its medical knowledge, its scientific knowledge, its pharmaceutical knowledge, et cetera. I don't know how we manage to do that, as a matter of fact.

Dr. LIPSETT. Well, I think we can also have a considerable element of pride in what we are doing for low birthweight infants. At any given weight level, Senator, say 500 to 1,000 grams, our neonatal intensive care units do as well as or better than any in the world, and that is so at any weight level. And our units are, I think, the place where people from other countries come for training.

Senator WEICKER. If that is the case—excuse me for interrupting because I am trying to learn here—if that is the case, and I can see that point as best I know as a lay person, then where does the matter go wrong?

Dr. LIPSETT. The matter goes wrong in that we have many more infants being born at very low birthweights, and no matter how good you are you are going to lose an appreciable number of these infants.

Ten years ago we lost 50 percent of infants under 3½ pounds. Now we lose about 25 percent. It is a great improvement. But we still have too many infants being born at these low birthweights, and that is the reason for our initiatives to study what starts labor prematurely, why infants don't grow and mature normally in utero, and the improvement of several aspects of neonatal care.

Senator WEICKER. I suppose the only point that I am trying to make is I am not satisfied that we are offering or making possible prenatal care to those that most need it. I suppose for the wealthier part of our economic strata, during the course of their doctors' visits and all that, they are going to get it, but for the poorer elements of society this should almost be an outreach program to get it through to them.

Dr. LIPSETT. That is certainly part of it, Senator. A good part of it. And this is where human learning and behavior comes in.

There are many women who know about and could utilize prenatal care but choose not to and who, as you say, come in when they are in labor. It is, in effect, a rather self-destructive behavior.

Senator WEICKER. But it is not just a question of their not knowing about it. You are also talking about people whose general knowledge is at the lowest level. That is why I am saying there has to be an outreach program.

I think it is only within the last several years that the educated wealthier elements of the population even learned how eating or lifestyle affected the mother. It is only recently that this has come to pass, and they are among the more educated elements of society who have access to knowledge and doctors. I am convinced, that if you want to go ahead and lower that rate there has to be an outreach here in terms of prenatal care to those mothers that are predominantly in our urban areas, et cetera.

What are we doing, in other words? All that we have been doing is to cut back the moneys. Am I correct? This also comes under our budget in other areas. I mean, we have cut back.

I am just wondering what we are doing. It seems that is where we have to go. I am not worried about the quality of our machines or our medical schools. I am worried about the outreach, about the prenatal programs, and obviously I am also worried about the status of the inner-city hospital, but that is a different story.

Dr. LIPSETT. Of course, everybody agrees that prenatal care is important. We don't know yet what elements of prenatal care are particularly important.

The Institute is now working with the District of Columbia and the Ford Foundation on a study on the significance of prenatal care, comparing one area of the city with another comparable area, where women of one area will get routine obstetrical care and women in the other will have an outreach program with very close followup and encouragement to use prenatal care.

That study will be just getting underway now. There are plans for additional studies at the Johnson Foundation, and we are interested in studies elsewhere in the country.

Senator WEICKER. Well, I think this is something you and obviously others in the spectrum here want to pay special attention to.

Gar, why don't you ask her or have Claudia ask the question that you pose?

Ms. INGRAM. I think that what Senator Weicker's question really should be directed to is whether or not there is as yet coordination between the Institute and, for instance, Dr. Brandt's office, which has policy responsibilities for the maternal and child health block grant, and within that block grant obviously there has been 15 percent set-aside for national activities.

Is this sort of information dissemination and outreach activity funded through perhaps the set-aside?

[Pause.]

Senator WEICKER. If you can't answer now——

Mr. ITTEILAG. I think Dr. Lipsett can probably help.

Dr. LIPSETT. I can speak to the coordination. Dr. Brandt has just set up a group from maternal and child health and from several other areas, including us, cochaired by Dr. Hutchins and by myself, addressing the problem of low birthweight infants from all of these aspects.

Mr. KAGANOWICH. Tony, I would add, one other thing you might want to look at here is what is being done through the Community Health Centers Program in terms of outreach, because I think it would be particularly effective there, and I have gotten the impression they may not be doing as much as they have been doing in the past.

Mr. ITTEILAG. I will talk to Dr. Brandt, and we will put something in the record at this point that further expands on this.

Senator WEICKER. All right.

[The information follows:]

### OUTREACH THROUGH COMMUNITY AND MIGRANT HEALTH CENTERS

Both community and migrant health centers have traditionally emphasized the need to assure access to all members of a defined population to early entry into the prenatal care system. The Bureau of Health Care Delivery and Assistance has developed a guidance to reaffirm this access issue in the following areas:

(1) Outreach/case findings: Each project is reassessing its means of assuring that all members of the defined population are enrolled in a prenatal system of care. Special emphasis is placed on at-risk populations.

(2) Staffing: Each project is reviewing its staffing patterns to assure that they have appropriate numbers of primary care providers to meet the defined needs. The projects are also reaffirming their compliance with the standards of the American College of Obstetricians and Gynecologists for prenatal care.

(3) Referral/linkage: All projects are reviewing their pernatal plans to assure that they are an integral part of a system of care. By doing continuous risk assessment, the pregnant woman and newborn child are assured of being at the appropriate risk level of care.

### CONTINUATION OF CORE GRANTS

Senator WEICKER. In our fiscal 1984 report, the committee strongly recommended that you continue the core grants which support mental retardation research centers.

What have you done in response to the committee's recommendation that the centers remain productive in doing quality work?

Dr. LIPSETT. Well, the centers were evaluated just 3 years ago and received rather high marks. We are maintaining the centers, although there will be an 8-percent downward negotiation this coming year, given the budget that we have.

As far as the productive work is concerned, our centers in mental retardation have been quite successful in attracting the very best people. We know they are the best people because they have a very good record in receiving RO–1's, project grants.

Senator WEICKER. Now, what would you need? You say it is 8 percent down. But what are you going to need to bring that to the level that will do the job in 1985? This isn't level programming. It is going down.

Dr. LIPSETT. About $2.2 million more for the entire centers program, with about $700,000 of that amount for the mental retardation research centers.

Senator WEICKER. And then last, the question I asked yesterday, where does the administration budget impact most harshly on your Institute?

Dr. LIPSETT. Well, I would say most harshly in perhaps three areas.

First, the loss of 100 research trainees will hurt us because we have responsibility for training in obstetrics and gynecology, in pediatrics, in mental retardation, human learning and behavior, and perinatology. We have been trying in discussions with the various professional societies to induce more physicians to come into these areas. Continued progress in the areas I have discussed depends initially on the continued entry of new young people into research.

Second, we won't be able to start several clinical trials, one on the efficacy of routine ultrasound in pregnancy, one on new contraceptive formulations, and one on a material for the treatment of a respiratory distress syndrome.

And, finally, I think that our Intramural Research Program will have to contract, based on current budget formulations.

Senator WEICKER. Your intramural?

Dr. LIPSETT. Intramural, which should be afforded the same consideration as the Project Grants Program. They are the same sort of scientists doing the same sort of work and doing it very well.

Senator WEICKER. Now, tell me about that just for 1 minute here. The distinction we are talking about, can you put this on an equivalent basis for me as compared to, let's say, competing grants?

How many competing grants do you have?

Dr. LIPSETT. Well, our intramural budget is $34 million, and our total Research Grant Program is approximately $200 million.

Senator WEICKER. The grants are $200 million?

Dr. LIPSETT. For all the grants, including the centers. The Intramural Program is a rather small fraction of the total amount that is funded for grants.

Mr. KAGANOWICH. Your competing grants are affording $49.8 million.

Dr. LIPSETT. Yes; I am talking about all of them.

Senator WEICKER. What I am asking is, your competing grants are estimated $49 million, roughly, 425. Now can you give me an equivalent in the intramural?

Mr. ITTEILAG. Perhaps if we took a third of that, because most grants are competing every third year, a comparable number for the Institute's Intramural Program would be about $10 million as compared to just competing. Otherwise, we would need to compare the total intramural with the total grant line rather than just with the competing.

Senator WEICKER. I want to pin this down, because I think maybe I am missing something here that I should be paying attention to. I know I have been paying a great deal of attention to the competing Grants Program. I am worrying whether I am not missing the Intramural Program in doing that.

Dr. WYNGAARDEN. The Intramural Research Program represents about 12 percent of our total budget. This year, the total estimate for the Intramural Program is $546 million compared to $537 million last year, so it goes up about $9 million or about 2 percent, roughly the same as the total request.

Senator WEICKER. And how did the Intramural Program fare last year? Can you remember?

Dr. WYNGAARDEN. Yes; it increased from $500 million in 1983 to $537 million in 1984, so it went up about 7 percent.

Senator WEICKER. And what did the competing grants go up?

Dr. WYNGAARDEN. The competing grants went up 14.8 percent last year.

Senator WEICKER. OK. Thank you very much, Dr. Lipsett. There will be other questions for response to the record.

I beg your pardon. I'm sorry, Senator Proxmire.

Senator PROXMIRE. It's all right.

Dr. Lipsett, you agreed with the chairman that the statistics on infant mortality in this country are not anything we can be really proud of, and you gave us some reasons for it. You indicated that one of the principal reasons is because of low birthweight.

Have you made any kind of a study or is any study available to you as to why birthweights are lower now than they were before? Frankly, I understand that one of the problems we have in this country is that it is a heterogeneous country. When we compare this country with Sweden, for example, I understand that the Swedes in Minnesota have a better health record than the Swedes in Sweden. But because we are a heterogeneous country, consisting of a tremendous number of different groups that have different levels of culture when they come here, and so forth, it's hard to compare us with a country that is homogeneous in its population. But the historical birth rate comparison, it seems to me, should be quite disturbing. We ought to have a good solid analysis.

Dr. LIPSETT. Well, there have been many analyses, Senator Proxmire.

Senator PROXMIRE. What do they show?

Dr. LIPSETT. They show, in fact, the actual incidence of low birthweight has been slowly decreasing in this country. Women are learning and working with decisions to improve their——

Senator PROXMIRE. Very slowly.

Dr. LIPSETT. Slowly. We still have too many.

Senator PROXMIRE. I thought you said there were many more instances of low birthweight children than there have been in the past. Was I wrong? Did I misinterpret that statement? Has the birthweight data been improving?

Dr. LIPSETT. It has been slowly improving.

Senator PROXMIRE. Well, I do agree wholeheartedly with what you and the chairman were talking about. It is critical that we do our best to explore the low birthweight issue further and to improve birthweights sharply.

Dr. Lipsett, your Institute seems to be supporting a substantial amount of research that, on the surface, would seem to be more appropriate for the mission of the Department of Housing and Urban Development or the Census Bureau. For example, you have awarded Washington State University approximately $46,000 to develop a new procedure for simultaneously correcting errors in two census age distributions and intercensal registered births and deaths by age. The research plan abstract says: "The new procedure has application to the areas of census evaluation, analysis of incomplete vital registration data, and life table construction."

Why wouldn't it be more appropriate for the Census Bureau or the insurance industry to finance that work?

Dr. LIPSETT. I cannot speak for the insurance industry or the Bureau of the Census. However, the NICHD has a research mission in the demographic sciences as well as the behavioral sciences. We are the only Institute, in fact the only area of Government, with a basic research program in the effects of immigration, and relationship to family structure, need for schooling, infant mortality, and so forth. This grant is a methodological project which will provide a technique of analysis that will assist the demographic community in using census information for research purposes. This type of research activity is similar to preparing drugs for distribution.

Senator PROXMIRE. Doesn't the Census Bureau do any kind of work of that kind?

Dr. LIPSETT. The Census Bureau is a data gathering agency, whereas the NICHD mandate is for research. This means that there may be projects dealing with census materials that are necessary for research, but not necessarily within the mandate of the Census Bureau.

Senator PROXMIRE. Do you coordinate this kind of study with the Census Bureau? Do they have any input?

Dr. LIPSETT. I think it is fair to say we coordinate it. We know what they are doing and what information they have on the tapes, and when there is a need for it, we take advantage of that.

Senator PROXMIRE. Dr. Lipsett, the Institute has provided Harvard with a grant of $51,000 plus indirect costs of another $30,000 for a project titled "Demographic Structure and Central City-Suburb Location." The research plan abstract says the analysis done with these funds, "will allow us to predict how specified changes in the population and prices of central city and suburban housing will alter households' choice of central city and suburban locations in a particular metropolitan area."

What does that research have to do with child health and human development?

Dr. LIPSETT. This grant will estimate how households of differing characteristics choose residential locations. It is the great mobility of households within metropolitan areas that creates a fast changing demographic structure. For example, in the area of infant mortality we have vital records of the deaths, but the movement within the city may hamper our understanding of patterns of infant mortality because we cannot measure the population accurately. In order to calculate infant mortality rates by characteristics of the population, researchers need information not only about the deaths but about the population. Patterns of metropolitan movement have great bearing on family structure, how the family survives in the city, and that information will be important in some of the problems we face, even in relation to low birthweight infants.

Senator PROXMIRE. On page 66 of your justification, you indicate that the motivations behind the initiation of smoking is an area of research interest to the Institute.

What work have you supported in this area to date and how much do you anticipate spending on smoking research next year?

Dr. LIPSETT. We supported 11 grants for $2.2 million in fiscal year 1983 and estimate funding $2.4 million in fiscal year 1984 and fiscal year 1985.

Senator PROXMIRE. Do you coordinate your smoking research with that funded by the Heart, Lung, and Blood Institute and, if so, what is the coordinating mechanism?

Dr. LIPSETT. Yes; there is an interagency committee on smoking and health.

Senator PROXMIRE. Can you tell us what the committee does?

Dr. L'ENFANT. Senator Proxmire, the Institute is mandated by law to have interagency technical committees which bring together all the governmental agencies which are involved with research relating to our programs and smoking, of course, is one of the most important activities of the committee.

Senator PROXMIRE. Is Dr. Löe still here?

Dr. LÖE. Yes, Senator.

Senator PROXMIRE. Do you mind if I ask Dr. Löe a couple of questions?

Senator WEICKER. Could I just let Dr. Lipsett go here on one last question for response now or for the record.

On the matter of low birthweight babies, I understand this might be the time to take a major initiative in that area, and I was just wondering what sort of initiative could be undertaken and why the timing might be right to start it now in 1985.

Dr. LIPSETT. Well, what we have proposed to the Department, Senator, that we undertake, we will begin in a limited way this fiscal year.

Senator WEICKER. I thank you very, very much.

Senator PROXMIRE. Could I ask just one more brief question of Dr. Lipsett.

Senator WEICKER. Go right ahead.

Senator PROXMIRE. Dr. Lipsett, as you know, recently there have been some sensational and revolting revelations about child abuse in California and elsewhere. I'm sure that people all over this country are terribly upset about that. We know child care facilities are critical as more and more families have both parents working. Although the problem of child abuse is not, strictly speaking, a biomedical issue, is your Institute doing any work in this area?

Dr. LIPSETT. Well, our investment in child abuse is very limited, Senator. It's not been one of the charges of this Institute and it is dealt with elsewhere in the Department. A related issue is that of the latchkey children.

Senator PROXMIRE. With what kind of children?

Dr. LIPSETT. Latchkey children. The fact that parents aren't home when children return from school and the effects on their behavioral adjustments are a concern of ours. Our Demographic and Behavioral Sciences Program is funding studies in this area. I mention this because it deals with some of the demographic points you mentioned previously.

Senator PROXMIRE. Thank you.

Senator WEICKER. Thank you very much, Dr. Lipsett.

Dr. Löe, you want to step up here for just a few minutes. Senator Proxmire.

Senator PROXMIRE. Dr. Löe, the National Institute of Dental Research has sponsored a $465,000 5-year study on the effects of orthodontia on psychosocial functioning. The grant award states that "Since approximately 70 percent of the general population has some form of dental-facial malrelations, the potential demand for treatment based on psychosocial benefits is great." But the Department has said that they have no intention of requesting public funds to pay for orthodontia.

My question is, why sponsor a study with public funds, when you have no intent of following up the study with a program to address the questions posed by the study? Isn't this a case of putting the cart before the horse? Given that the deficit is around $200 billion, why should this study be funded?

Dr. LÖE. Behavioral aspects of craniolfacial disorders and disfigurements are part of the mission of the NIDR which is to conduct research to improve the Nation's oral health. Behavioral factors affect oral functions and health. It is proper for the NIDR to conduct scientific research in this area; it is up to others to carry forward dental care policy.

Senator PROXMIRE. Do you have any idea who would follow up on this work? Who would use the results of the study?

Dr. LÖE. I am sure the public at large would use it. The profession could use it. State and local dental health organizations could also use the information.

Senator PROXMIRE. Has there been any expression of support and interest by the dental profession in following up and using the study results?

Dr. LÖE. Senator Proxmire, from our point of view, this is a straightforward behavioral problem related to psychological, physiological, and functional aberrations which warrants research.

Senator PROXMIRE. Did you make any effort to find a private sponsor for this study?

Dr. LÖE. No; we have not.

Senator PROXMIRE. Why not?

Dr. LÖE. I am not sure who would be interested in funding such research. Possibly insurance companies or philanthropic organizations might be candidates and it would be interesting to see if they could be made a part of an institute funding mechanism.

Senator PROXMIRE. Now, the Institute is sponsoring a number of behavioral studies on topics such as controlling stress during dental procedures—which bothers all of us—children's perspectives of the nitrous oxide experience, and dental anxiety; behavioral approaches to fear reduction. I fear the $200 billion deficit we are facing much more than I fear going to the dentist, although I fear both of them greatly. Why should the committee not eliminate this type of study until we get the deficit under control? It seems to me that if there is any area in which the dentists of this country would do some of their own work—and they've done a good job, I must say—it's in easing the pain and the fear that all of us have when we get in a dental chair and open our mouths and the dentist starts probing around. But the dental profession has improved their ability to handle fear greatly in my lifetime. I wonder why we need to conduct studies at the public expense—at taxpayers' expense—on these kinds of behavioral studies.

Dr. LÖE. There is more to be learned about fear and anxiety in both children and adults in relation to the dental care situation. We know that approximately 15 percent of the population never see the dentist because of fear. We would like to know why this is so and what can be done about it.

There have been improvements in this area. Behavioral studies have led to ways of educating and reducing fear in children so that they now approach the dental office with confidence.

Senator PROXMIRE. Are you cooperating in these studies with the dental profession in any way?

Dr. LÖE. Yes; there are other studies supported by other organizations, but this happens to be a grant application submitted to the NIDR. It is within our purview, and I feel confident that this will result in a meaningful scientific contribution.

Senator PROXMIRE. Thank you, Mr. Chairman.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you, Dr. Löe.

There will be some additional questions for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: Formulation of the FY 1985 budget began with an NICHD request in the spring of 1983. During the FY 1985 budget process, the Institute was given several opportunities to present its budget priorities and the impact of various options on our programs. The final budget, however, was based more on overall guidelines for funding mechanisms, such as research project grants and training.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain.

Answer: The NICHD will fund 12 fewer competing research project grants in FY 1985 than in FY 1984, 13 fewer research career program awards, 86 fewer full-time training positions and 5 fewer R&D contracts. Nevertheless, within the FY 1985 budget, high priority research will be vigorously pursued, and a modest implementation of the Institute's prevention of low birthweight initiative will be possible. In other respects, the budget for FY 1985 will provide for similar levels of program activity as in FY 1984.

Question: To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer: The competing research project grants--those which are new or renewal--will be reduced an average of 4% in FY 1985. The noncompeting continuation grants will not be subject to reduction and hence, will be funded at full cost levels. It is anticipated that no important research will be delayed or eliminated as a result of the FY 1985 funding of grants below full cost levels.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84?

Answer: The NICHD will support 44 research centers in FY 1985, the same numbers as in FY 1984. It is estimated that these centers will be reduced by an average of 7.7% from full-cost levels in FY 1985. In FY 1984, the reductions averaged approximately 2.8%.

Question: What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: The rate at which results of basic research are translated into prevention and treatment may be affected to some extent. However, the FY 1985 funding of research centers at the same level as FY 1984 should not have significant adverse impact.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: The NICHD will support 537 full-time training positions (FTTP) in FY 1985, a reduction of 86 FTTPs from the FY 1984 level of 623 FTTPs. It is difficult to predict exactly how much effect this will have in the future, but there is no question that decreases in the number of FTTPs that we support will result in fewer trained researchers for the future. The NICHD training program is one of our highest priorities.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: It would require an additional $8,515,000, or a total of $288,693,000, to maintain the NICHD at the FY 1984 level of activity.

Question: The Budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Answer: The NICHD share of the NIH full-time-equivalent (FTE) reduction is 19 FTEs, of which 5 FTEs will be from intramural research, and the remaining 14 FTEs from research management and support. It is difficult to assess the precise impact these reductions will have on our research programs. We will make every effort to minimize the adverse impact of this reduction.

## LOW BIRTHWEIGHT BABIES

Question: I understand the timing may be right to undertake a major initiative in the field of infants who do not weigh enough when they are born. I gather low birthweight can lead to mental retardation and metabolic problems, among others. What sort of initiative could be undertaken and why is the timing right to begin it in Fiscal 1985?

Answer: The NICHD could undertake a research initiative on the prevention of low birthweight--the major factor contributing to infant morbidity and mortality and the most important problem in maternal and child health today. The initiative would include research on intrauterine growth retardation (IUGR) and premature labor. The time is right because the scientific opportunity exists and the societal need is present. It is particularly relevant to the needs of blacks where the incidence of low birthweight is roughly double that experienced by whites. This initiative may also be expanded as a result of recommendations from the HHS Task Force on Black and Minority Health Problems.

Question: How much will such an initiative cost -- and is the money provided in your budget?

Answer: We estimate that in FY 1985 this initiative will cost $3.7 million over the President's budget request, which includes $1.8 million for this initiative, for a total of $5.5 million, although this may be modified by the recommendations of the Task Force.

Question: Could you provide me with a listing of what research on low birthweight can be done in FY 85 and what costs this would require in future years?

Answer: The research to be conducted in 1985 would fall into the two categories just mentioned plus clinical testing and educational efforts.

1. Intrauterine Growth Retardation (IUGR)

   a. Fetal Growth Factors. The role of a number of substances in regulating fetal growth will be studied.

   b. Biological Predictors of Fetal Growth. There is evidence that certain measurements may allow diagnosis of IUGR early in pregnancy and permit early intervention. These measurements will be studied to assess their predictive value.

   c. Perinatal Emphasis Research Centers (PERC). Two new Centers would be added: one to focus on control of fetal growth and IUGR and the second to focus on perinatal pharmacology and toxicology.

2. Premature Labor

   a. Biochemistry of Labor. Current efforts will be expanded to focus on abnormalities that may trigger labor prematurely.

   b. Premature Rupture of Membranes. Studies will be conducted on amniotic membranes to search for the mechanisms responsible for early rupture.

3. Cooperative Network of Maternal-Fetal Medicine Units. A network of leading obstetric maternal-fetal medicine units that care for women of high risk for low birthweight will be established to conduct clinical trials of new therapies.

4. Education Efforts. The Institute will launch an expanded education effort targeted to high-risk women and physicians. Examples of topics include early entry into prenatal care, smoking as a cause of low birthweight, and recognition of signs of early labor to permit intervention.

The cost of the initiative in 1985 is estimated at $5,500,000: in 1986 the cost is estimated at $8,000,000.

Question: I really can't believe that after all of this time we still don't know what triggers labor in a pregnant woman. What can you tell us?

Answer: Intensive and continuous research has been under way for many years in the area of initiation of labor. Although it seems strange, new knowledge clarifying aspects of the onset of labor frequently generates new questions requiring answers. This is the essence of research. In addition, development of new and sophisticated methodologies is permitting further refinement of techniques applicable to this fundamental research question.

Specific research progress has been made towards understanding of a very complex biologic phenomenon. For example, contractility of uterine muscle can be stimulated by certain hormones, such as prostaglandins. The recent explosion in prostaglandin research has made it clear that they play a significant physiological role in labor by causing uterine contractions. Research efforts are now directed toward understanding what factors influence prostaglandin formation; fetal control of these factors is a realistic possibility. Other factors, such as maternal infection, may also be important. A clinical trial is being initiated at the present time to study maternal infection. Certain other hormones inhibit uterine muscle contractility, whereas pharmacologic agents are now available which will arrest preterm labor in some cases. Many other factors are thought to play a role in parturition. These are being investigated with the latest techniques at several levels: intact organism, organ tissue, cellular, and subcellular levels.

Question: We have been told that the cost in physician and hospital care for low birthweight babies is about $2 billion a year. Can you verify this — and could the initiative you have discussed help to reduce that cost?

Answer: That figure probably is an underestimate. Back in 1980 Dr. Peter Budetti and his colleagues at the Health Policy Program, University of California, San Francisco, developed a Case Study on "The Costs and Effectiveness of Neonatal Intensive Care." At that time they estimated the cost of neonatal intensive care units to be $1.58 billion dollars. Dr. Budetti, who now is on the staff of Congressman Waxman, tells me that the current cost is closer to $3.0 billion dollars. These costs cover only hospital costs. Of course one would have to add to those figures the physician costs not billed through the hospital and lifelong care costs for the treatment of handicaps. The initiative would provide the knowledge needed to prevent low birthweight and would reduce these costs considerably.

## IN VITRO FERTILIZATION

Question: Doctor, I understand that you are losing one of your scientists in the field of test tube fertilization because each experiment must be approved by an Ethics Advisory Board and there currently is no Board. What goes on here -- and what is this doing both to your research in the field and the need for research generally on this matter?

Answer: In the absence of an Ethics Advisory Board, NIH may support *in vitro* fertilization research on animals. Because research on human *in vitro* fertilization is a sensitive and complex issue, the Department is proceeding with great caution in considering the reestablishment of the Ethics Advisory Board. In the meantime, research in the field is being supported by small foundations, private groups, and patient fees.

Question: Have there been instances of successful implants of embryos fertilized in a test tube and, if so, why do you need more research on the subject?

Answer: Yes, there are many instances in this country and abroad of human eggs fertilized in vitro that have developed into normal healthy babies. However, these successful instances represent a very small proportion of the attempts to achieve successful pregnancies through human in vitro fertilization. Aside from the deep disappointment and heavy expense borne by couples involved in failed attempts at human in vitro fertilization, these failures testify eloquently and insistently to the need for more research to provide the knowledge required not only for improvement of the failure rate, but also for the safety and efficacy of the clinical procedures for human in vitro fertilization that are being used increasingly to alleviate human infertility in the United States.

Question: What work can you do in this area in the absence of an Ethics Advisory Board?

Answer: In the absence of an Ethics Advisory Board, NIH support for research on in vitro fertilization is restricted to relevant research on animals. We are able to study children born after in vitro fertilization, and are about to begin such a study.

## INFANT MORTALITY

Question: The Subcommittee is concerned about black infant mortality which appears to be about double that of white infant mortality. The availability of health services could be a key factor in reducing black infant mortality, but research also may play a role. What can you tell us about this problem -- what have you found?

Answer: Infant mortality has many causes but the most important factor which impacts on black-white differences is the high rate of low birthweight among blacks. In most published comparisons this rate exceeds the white rates by a factor of about 2. Low birthweight and infant mortality are more common among lower socioeconomic groups and this appears to explain some but not all of the black-white difference. Moreover, the biological mechanisms which account for excess preterm births in black women have not been fully uncovered. We know that hypertension is more common in the black community and this may play a modest role. A number of reports have suggested that vaginal organisms (germs), which used to be thought to be benign, may cause some preterm births, and the NICHD has initiated a large study involving black, white and hispanic women to examine the role of these organisms. Single parent families are more common in the black community than the white community and there may be social stresses associated with this, which could have deleterious effects on the outcome of pregnancy. Teenage pregnancies are also more common and probably play a small but significant role in contributing to the difference. Despite these several leads the full difference between the white and black communities in infant mortality is not understood. NICHD is actively investigating the causes of the inter-ethnic differences in low birthweight and infant mortality. Besides the infection study noted above, initiatives on the role of hypertension and plasma volume, studies of the Sudden Infant Death

Syndrome, and interview studies of mothers who have recently given birth to small infants are all being pursued. The usefulness of training women to recognize the premonitory symptoms of labor, of drugs which stop the progress of early labor, and of hormone therapies which may inhibit the onset of early labor are all under active investigation. We believe that our understanding of these issues will be significantly better within a few years.

Question: To what extent do you coordinate your work with other components of the Public Health Service to make sure that your research findings are broadly available?

Answer: Active and continuous coordination is maintained among NICHD and other components of the Public Health Service. In addition to informal communications regarding specific problems there are also formal interagency meetings. Institute staff serve as members of several interagency and departmental committees, and staff of other components of the Public Health Service are members of NICHD committees. The Directors of the Division of Maternal and Child Health and of the NICHD are co-chairing a low birthweight work group which was recently established by Dr. Brandt and includes representation from the National Center for Health Statistics, the National Institute of Mental Health, the Centers for Disease Control, and other representation from the Health Resoures and Services Administration and from the NICHD. NICHD participated in and contributed to the recent deliberations of the Institute of Medicine's committee for a study of priorities for the prevention of low-weight births. This group included both government and private agency representation. The Institute has been in touch with the Food and Drug Administration on a variety of issues including the upcoming study of infection and low birthweight. We are working in close collaboration with the government of the District of Columbia on studies of the precursors of premature birth. The Institute has also worked closely with a number of state health departments in analyzing maternal and child health issues. There is significant interchange of professional personnel between agencies of the Public Health Service, and former NICHD employees are located in a number of other units with interests in maternal and child health. They provide a useful informal communication network, which has led to several joint publications.

## MENTAL RETARDATION RESEARCH CENTERS

Question: In our fiscal 1984 report, the Committee strongly recommended that you continue the core grants which support Mental Retardation Research Centers. What have you done in response to the committee's recommendation?

Answer: The NICHD has continued support of the core grants and provided a slight increase in support for each of the Centers in order to combat erosion in the programs due to inflation. The MR Research Centers continue to occupy a central place in the Mental Retardation Program.

Question: Are the Centers remaining productive and doing quality work?

Answer: The MRRCs continue to be highly productive. One indication of this is that their investigators compete favorably for direct support of research and training grants both from NICHD and from other agencies, public and private, which support research. The MRRCs have over 10 million dollars in research and training program support from the MRDD Branch and another 3 million from other programs in NICHD. These totals do not include the core grant funds. Staff maintain frequent contact with researchers and administrators at the MRRCs. Research highlights from the MRRCs are reported annually by staff.

Question: The Subcommittee understands that your are proposing level funding of $8 million for the 12 mental retardation research centers. What will a level appropriation do to the ability of the centers to maintain the same effort as in fiscal 1984?

Answer: The FY 1984 funding level of $8 million for these centers was an increase of $657,000, or almost 9% over FY 1983. Funding the centers in FY 1985 at the same level as FY 1984 will result in a decline in purchasing power of some 4.9%, and we would anticipate a concomitant decline in the level of effort.

Question: To what extent are the mental retardation research centers the major focus of your Institute's efforts in the mental retardation field?

Answer: The MRRCs are to a great extent a major focus of the NICHD efforts in the mental retardation field, and this is evident by the percentage of total MR funding which goes to these centers.

Question: How much of your MR budget will go into these centers in fiscal 1985?

Answer: In addition to the $8 million of center core grant support, there will be approximately $13 million of NICHD funds awarded to these institutions in FY 1985, representing some 64% of the total extramural funding of the NICHD's Mental Retardation and Developmental Disabilities Branch.

## EQUIPMENT AND FACILITIES

Question: Earlier in these hearings we questioned Dr. Wyngaarden about the problems of obsolete research equipment and deteriorating research facilities. What's the situation in the child health field -- both with regard to intramural and extramural research? Is there sufficient equipment -- is it up to date?

Answer: The intramural scientists at NICHD have the same needs for scientific equipment as their counterparts elsewhere. Generally, we have most of the kinds of laboratory equipment that we require, but some of that equipment is getting old. Examples of the types of equipment that need to be kept current are mass spectrometers, scintillation counters and ultra centrifuges.

Question: What about facilities? How much deterioration do you find and what is the impact on the research effort?

Answer: Much of the laboratory space occupied by NICHD scientists is in older buildings which are in need of modernization. The rehabilitation of the laboratory buildings should alleviate this situation somewhat.

## CONTRACEPTIVE DEVELOPMENT

Question: The Subcommittee notes that only about $8 million -- about 9% of your request for population research -- is spent on development of new and more effective contraceptive methods. Why so little? Don't you regard this as an important area?

Answer: We regard this as a very important area of research. The Contraceptive Development program identified in the NICHD budget at a level of $8,180,00 for FY 1985 is exclusively for R&D contract support. More basic studies of reproduction, supported by grants, are also critical for the eventual development of new and more effective contraceptive methods. The estimate for contraceptive development R&D contracts in FY 1985 represents the anticipated response from the research community to NICHD requests for contract proposals.

Question: How do you establish your priorities for funding in population research which includes contraceptive development?

Answer: There are several ways in which priorities are established within the overall context of population research. Establishment of priorities does differ to a degree between the basic research programs where the bulk of support goes to the applied programs where priorities are established by the Institute with advice from outside experts. Within its grants program the Institute established priorities by emphasizing specific areas of research that require special attention, such as research on causes and alleviation of human infertility. In the applied programs, such as contraceptive evaluation, priorities are given to the non-contraceptive effects of the various family planning technologies that pose a health problem to the user or which on occasion may be beneficial. In contraceptive development, priority is given to projects that have the potential to result in improved methods of family planning. Many of these projects have been described in the OTA report.

Question: We understand that the Office of Technology Assessment has recommended that far more be spent on contraceptive development than you are planning. What did OTA propose -- and what research opportunities did it cite as not being exploited because your budget is too low?

Answer: The OTA report identified a number of contraceptive technologies that were likely to be developed by 1990 and those which were possible by 1990 but prospects for which were doubtful. The report did not single out any specific opportunities that were not being pursued by NICHD due to funding difficulties. It did indicate that additional funding could have a significant impact on the total efforts in contraceptive research. Current funding levels do permit support for the most promising leads in the field and additional monies would allow for a broader investigation of the less developed leads. Among the "likely to be developed by 1990" leads that NICHD has not pursued actively are: 1) safer oral contraceptives; 2) improved IUDs; 3) steroid vaginal rings; 4) prostaglandin analogs for self-administered induction of menses. However, the above leads are being pursued by pharmaceutical companies and other public sector contraceptive development organizations.

## POPULATION STUDIES

Question: I understand you have some long-range studies underway into the changing role and structure of the family and the impact of jobs and career on child bearing. What is the status of these studies and do you cooperate with other federal agencies in gathering the information you require?

Answer: A number of projects in the population area address the changing American family. Some have focused on better measurement of the patterns of divorce and remarriage, especially as it relates to the structure of families and households where there are children. Other scientists are addressing the causes and consequences of such changes for children and adults alike. We have emphasized the use of available data and in doing so we have cooperated with a number of federal agencies. We have worked with the Bureau of the Census to supplement the Current Population Survey to provide data on marriage and fertility patterns. This enables us to collect information for research in conjunction with an ongoing Census survey. The data are then available to investigators through public use tapes, and the analysis is supported under the grant mechanism after scientific peer review. The cost varies with the extensiveness of the data, but we have found this to be a cost-effective way to obtain resources necessary for studying important issues in population research.

In regard to the impact of jobs and career on childbearing, we have a project with the Department of Labor. Their ongoing National Longitudinal Survey--Youth Cohort has proved to be a valuable vehicle for NICHD support. By adding questions on the fertility histories of the respondents, we are able to provide a resource that would be virtually impossible for the individual scientist to duplicate. The complete data tape will provide detailed data not only on childbearing and family building, but on education and occupational behavior, factors often closely linked to demographic processes. In addition, questions have been added about prenatal care and infant and child health. This has been a very satisfactory interagency agreement which will provide a valuable data set for research relating to adolescent pregnancy and childbearing, the factors associated with prenatal care and low birthweight, and the interrelationship of fertility behavior with other life events.

Question: What is the budget for these studies and is there any problem with getting the other federal agencies to put up their share of the funds?

Answer: Over the past four years, these studies have averaged approximately $550,000 per year, and we estimate a similar amount in FY 1985. Other agencies share the costs by providing the means by which much of the data is collected.

## MENTAL RETARDATION RESEARCH

Question: What new findings are coming from your program of support for research on mental retardation?

Answer: New findings are coming from the following areas:

## Down Syndrome

Down syndrome is the most common readily identifiable genetic condition associated with mental retardation. The condition is characterized by the presence of an extra chromosome 21 in the cells. A number of laboratories are investigating various aspects of Down syndrome, including basic studies relevant to the molecular biology of the condition. Six genes have now been "mapped" on human chromosome 21. Since the basic molecular structure and function of these genes are difficult to study on human subjects, a mouse model has been developed with genetic similarities to Down syndrome. These mice are smaller than their normal littermates, have a high frequency of congenital heart defects, their brains are small and less cellular, and the base of the skull is flat. These abnormalities are commonly found in Down syndrome.

In addition, three of the six genes that have been "mapped" on human chromosome 21 have also been "mapped" on mouse chromosome 16. The mouse model is distributed to investigators which will help to facilitate biomedical and behavioral research on Down syndrome.

## Phenylketonuria

Phenylketonuria (PKU) is a genetic disorder which is associated with severe mental retardation, behavioral problems, epilepsy, and other signs of neurological impairment. Newborn screening programs for PKU have resulted in the identification of affected babies who are then placed on a special diet low on phenylalanine. The developmental disabilities that are associated with PKU have been averted by the introduction of the special diet.

A diet restricted in phenylalanine impairs a child's opportunity to share the same food that his family and friends eat. This is particularly true in school when socialization takes place during meals. A study designed to determine the effects of random assignment, with parental consent, to either continue on the diet, or to discontinue and be free to eat a normal diet, will be completed this year. The investigators have concluded that despite early and optimal treatment, high phenylalanine levels after six years of age represent a risk factor to which many of the PKU children who discontinued their special diet are vulnerable.

An emerging problem that NICHD is currently addressing is the effect of high levels of phenylalanine during pregnancy on the developing fetus. Since the babies of PKU women who are maintained on a normal diet during pregnancy are known to be at a high risk to be mentally retarded and physically impaired, the Institute has recently initiated a clinical trial on the effects of phenylalanine restriction begun prior to and during conception on pregnancy outcome. Several clinics in 40 states will enroll PKU women in the study and will periodically assess their biochemical and clinical status during the course of their pregnancy. Their babies' development will be evaluated for several years and will be compared with control subjects.

Using recombinant DNA technology, an NICHD-supported investigator has cloned the gene involved in PKU. In addition, the gene will lead to the development of a reliable genetic mapping method for the identification of carriers and affected subjects, and for the prenatal diagnosis of PKU.

Metachromatic Leukodystrophy (MLD)

Metachromatic leukodystrophy (MLD) is a rare, recessively inherited disorder of lipid metabolism. It causes progressive intellectual degeneration and childhood death. A population study has improved diagnostic procedures for MLD useful in identifying family members as carriers, homozygous and normal. These findings will be useful in antenatal screening and genetic couseling.

New Inherited Diseases

A team of investigators has elucidated the enzyme defect in some new lysosomal storage diseases by chemical analysis and specific enzymatic assays. This has improved control of these devastating mental retardation syndromes by permitting prenatal diagnosis and informed genetic counseling.

Chorionic Villus Sampling - A New Research Opportunity

Following the demonstration of the safety and accuracy of amniocentesis for the prenatal diagnosis of genetic disorders about 10 years ago, about 30-40 percent of women over 35 years who become pregnant undergo this diagnostic procedure. But this procedure has some drawbacks, among which are the limited amount of fetal cells that can be recovered from the amniotic fluid; the lengthy wait before the cells can be analyzed and a diagnosis made; and the procedure cannot be done safely before the 14th week of pregnancy in most cases.

Chorionic villus sampling (CVS) is a diagnostic procedure which can be done as early as the 8th week of pregnancy. The NICHD will soon embark on a prospective, randomized trial to assess the safety and accuracy of this procedure compared to amniocentesis. Since CVS is applicable much earlier in pregnancy than amniocentesis, it may be more acceptable to the patients and to the general public. Furthermore, chromosome analyses may be completed within a few hours to a few days, as opposed to the 2-4 weeks required for culture of amniotic fluid cells. Finally, the amount of cellular material obtained can be sufficient for the application of recombinant DNA studies. This latter approach may provide solutions to some of the complex cytogenetic problems that have been unresolvable by microscopic analysis.

Question: What will be your areas of emphasis in mental retardation research?

Answer: Major emphasis will be given to research on genetics and genetic disorders, high-risk infancy, and the problems and stresses of families with mentally retarded and developmentally disabled children.

Advances in medicine and surgery, and application of public health measures such as improved nutrition and immunization programs, have resulted in a diminished contribution of environmental factors and infectious diseases to mortality and morbidity. As a consequence, genetic disorders have become increasingly prominent in the etiology of human diseases. Surveys of hospital admissions have shown that 10-25 percent of patients have a disorder which is at least partly genetic in causation, and 5 percent have a disorder which is entirely genetic in origin. Recent advances in genetics and cell biology have contributed significantly to our knowledge of gene structure, organization and function. More genes are being cloned each year and the prospects for correcting genetic abnormalities are theoretically feasible. More research in genetics is needed and will be facilitated to maintain the momentum which will eventually lead to the primary prevention of genetic causes of mental retardation.

Early diagnosis and early intervention for infants born at high-risk due to biological and/or environmental insult is seen as a promising area for the prevention of some forms of mental retardation and developmental disability. The research strategy calls for the development of infant assessment measures for identifying high-risk infants and the development of effective interventions which minimize the effects of early damage on later development.

The psychosocial and medical stresses on families with mentally retarded and/or developmentally disabled children are profound. Research aimed at the prevention of mental retardation and developmental disabilities is fundamental to lifting the burdens on families posed by these handicapping conditions and will be advanced. The prospects for prevention of all these handicapping conditions remains a distant goal and, therefore, research aimed at reducing associated family problems and stresses will be given special emphasis.

Question: What role do the Mental Retardation Research Centers (MRRC) play in this program?

Answer: The MRRC Program is the centerpiece of the Mental Retardation Research Program. The Centers compete successfully for about half of the research and training support awarded by the MRDD Branch. Investigators from the MRRCs participate in NICHD sponsored research workshops as a result of their high visibility in the various fields of MR research. Research training in the Centers has contributed large numbers of researchers who now specialize in MR research. The Centers also serve as vehicles for attracting high quality researchers to the field of Mental Retardation and facilitate the development of new research programs relevant to solving the problems of mental retardation. Staff can approach investigators in the MRRCs to undertake studies of specific research problems as they may arise. A good example is the developing interest in research on the impact of mental retardation on families which is occurring at several of the MRRCs.

Question: How much is in your request for MRRC center grants? Isn't this the same amount as for fiscal year 1984?

Answer: The FY 1985 request for the MRRCs is $8,000,000, the same level as FY 1984.

Question: How can these centers do more, or even maintain their previous levels of research if the centers funding doesn't even begin to address the higher costs of doing research, let alone new initiatives in this important field?

Answer: The FY 1985 funding of the MRRCs at the FY 1984 level will result in a decline of purchasing power of some 4.9 percent, however, it is anticipated that even with a modest decline in activity, those centers will continue to contribute substantially to the overall research effort in the mental retardation area.

## SUDDEN INFANT DEATH SYNDROME

Question: The Subcommittee has continued to follow the research effort to find the cause of Sudden Infant Death Syndrome (SIDS). Your special report to the Subcommittee said that you appear to "have reached a crossroads in SIDS research." What leads you to this conclusion and is it a pessimistic one?

Answer: An active research program on SIDS has been supported by the National Institute of Child Health and Human Development over the last 15 years. The major emphasis has been on studies of sleep physiology and cardiorespiratory patterns and their development in infants during their first year of life. In addition to yielding knowledge relevant to SIDS, these studies have expanded our understanding of the normal physiology of many basic functions during development. This knowledge is not yet complete. Studies are continuing along newly identified and promising approaches. "Crossroads in SIDS," as mentioned in the Special Report to the Subcommittee, was a descriptive term to indicate changes in research directions. "Reaching a crossroad" does not represent a pessimistic view, but rather highlights the fact that research is an active process where periodic evaluations identify new short-term goals without losing the overall objective, in this case the prevention of SIDS.

Question: What avenues of new or promising research will you pursue in Fiscal 1985 and what funding level do you plan?

Answer: A SIDS planning meeting was convened in September, 1983, to review accomplishments and discuss future research directions. The recommendations presented stressed the need to expand knowledge about brain development (more specifically brainstem) where cell populations involved in the regulation of respiration and sleep/wake states are located. New semi-automated computer assisted quantitative methodology has become available and can be applied to research in this area. The Institute is planning to encourage research to examine specific aspects of brainstem cells in SIDS and non-SIDS victims. In addition, the existence of specific rhythms in many biologic functions has raised questions regarding the possible relationship of SIDS to immaturity of some or abnormal coordination between several oscillator systems essential to normal development and adaptation to stress. Research in this area will be stimulated. Funds for SIDS in FY 1985 will be $18,300,000.

## BUILDING 33

Question: In FY 1979 construction funds were appropriated for an intramural laboratory building for the NICHD, but the funds were subsequently rescinded. At that time, the building's main purpose seemed to be the consolidation under one roof of a widely-scattered program. Does NIH feel that the Child Health building is an important priority, and are the reasons for building it still the same?

Answer: The NIH Director considers the Child Health Building to be an important project as the reasons for constructing this facility are the same now as they were in FY 1979.

Consolidation of NICHD intramural space, in addition to creating greater opportunity for scientific interchange, would also promote greater efficiency in utilization of shared facilities and equipment, eliminating unnecessary duplication; improve administrative communications within and between the laboratories; and prevent contamination of tissue cultures and loss of other experimental materials now exposed to undesirable conditions such as crowding, exposure to loading docks, and proximity to laboratory animal holding facilities.

In addition, current data concerning assignment of space indicates that in the NICHD intramural program, the average is 140 sq. ft. per person. This is the lowest figure at NIH, significantly below the NIH average of 240 sq. ft/person, and even further below the government standard for laboratory space of 400 sq. ft/person.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### URBAN RESEARCH

Question: Dr. Lipsett, the Institute has awarded about $65,000 to the Urban Institute to describe and explain changes from 1970 to 1980 in the gap between city and suburban average incomes for each of the 100 largest metropolitan areas in the United States. How will this research award contribute to medical progress?

Answer: Within the mandate of the NIH, the program of the Center for Population Research is directed to research on the causes and consequences of population growth and change. Patterns of population change are important for the health of the nation, and some projects assess the more direct linkages and others the less direct. Recent research has indicated that population movement into and out of American cities is becoming increasingly selective. This process, which has its beginnings in the decade of the 1970's, has the potential to alter the demographic profile of major American metropolitan areas. The grant awarded to the Urban Institute would examine how these changes have affected a crucial indicator of individual and community well-being, i.e., income. If, for instance, metropolitan areas should separate into zones that differ markedly in terms of demographic characteristics, then the demand for all types of public and private services could be greatly affected. This applies to medical services in particular, and if, for instance, an area in a metropolitan area should become dominated by poor female-headed households with many children or by affluent households composed of mature adults with no children, then the types of medical services rendered from both public and private sources would be forced to adjust radically to accommodate these changes. This project will help us understand the economic and demographic dimensions of these changes and to anticipate the implications for the future of the 100 largest metropolitan areas in the United States. As such, this project has relevance for the population mission of the NICHD as well as usefulness for the larger medical community.

## PROJECT CONTRACTS

Question: Last year at this time you estimated expenditures of $26.6 million for project contracts in fiscal 1984. The current estimate for 1984 is only $20.5 million. Why was last year's projection so wide of the mark?

Answer: Over the past few years, NICHD management has looked closely at new contract program proposals for the possibility of alternative funding as grants. In addition, several research projects funded by contract have been completed. In FY 1980 NICHD contract obligations were $25,386,000, but declined to only $19,149,000 in FY 1983. Preliminary plans for FY 1984 to restore contract funding to previous years' levels were amended in order to fund higher priority research in grant funding mechanisms.

## PRINTING AND REPRODUCTION

Question: Despite a substantial increase in your 1984 budget your projected printing costs have fallen from an estimate of $475,000 contained in last year's justifications to $329,000 currently. Why was your initial estimate $146,000 too high?

Answer: Due to government-wide controls on printing and publications, actual NICHD printing and reproduction obligations fell from $375,000 in FY 1982 to $303,000 in FY 1983. The FY 1984 estimate of $475,000 was based on a FY 1983 estimate of $437,000. The current FY 1984 estimate reflects the lower actual obligations in FY 1983.

## NATIONAL EYE INSTITUTE

## STATEMENT OF DR. CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN DIRECTOR, NATIONAL INSTITUTES OF HEALTH

EDWARD McMANUS, DEPUTY DIRECTOR, NATIONAL EYE INSTITUTE

ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

### PREPARED STATEMENT

Senator WEICKER. Next to appear before the subcommittee is the National Eye Institute, which is responsible for research relating to diseases of the eye.

The budget request for the Eye Institute is almost $158 million or slightly more than $3 million above the fiscal 1984 level.

Here to testify in support of the request is Dr. Carl Kupfer, Director of the Institute.

Doctor, why don't you proceed. I might add, all statements will be included in their entirety in the record. You may proceed with a summary of your statement and the introduction of your associates.

[The statement follows:]

## STATEMENT OF DR. CARL KUPFER

Eleven million Americans suffer some degree of visual impairment, and half a million are blind. The aim of research supported by the National Eye Institute (NEI) is to reduce this tragic burden of visual loss by improving the prevention, diagnosis, and treatment of the vast array of sight-threatening disorders that continue to claim new victims each year.

Today I want to report on research efforts that will bring us significantly closer to achieving this goal. I will be discussing recent and anticipated advances in the management of several eye disorders that are major contributors to visual disability in this country. These include:

- a potentially blinding disorder caused by a fungal disease that is endemic in the midwestern United States;
- an inflammatory eye disease that is responsible for 5 to 10 percent of the visual impairment in this country;
- the most common form of glaucoma, the eye disease which is the leading cause of visual loss in this country;
- the sight-threatening retinal disease that is estimated to affect 51 percent of the Nation's 11 million diabetics; and
- a degenerative disease that is the leading cause of visual impairment among elderly people.

Then I want to tell you about an entirely new field of research opening up in the visual sciences--the application of highly sophisticated biochemical and molecular genetic techniques to the study of hereditary and other blinding eye diseases. We believe that the progress now taking place in this area will in time carry us far beyond our present therapeutic capabilities and furnish us with treatment methods which were unimaginable just a few years ago.

The first research advance that I would like to report to this committee is the outcome of a recent nationwide clinical trial that the National Eye Institute supported. This study showed that laser therapy can benefit many people whose sight is threatened by ocular histoplasmosis, an eye disease that occurs in some individuals who have been infected with the fungus *Histoplasma*. It has been estimated that 90 percent of people in the Midwestern United States have been exposed to this fungus, and so have many people in certain parts of the East and South. Years after exposure, it is postulated, abnormal new blood vessels may grow and destroy the retinal cells responsible for central vision. The study results reported this year demonstrated that appropriately timed laser treatment can obliterate these new blood vessels and prevent severe visual loss in many patients with ocular histoplasmosis. Laser therapy cut in half their risk of losing central vision.

In the past year, there has also been great progress in research on uveitis, an inflammatory disease that attacks tissues within the eye and causes much visual impairment nationwide. As I told this committee last year, NEI scientists were conducting pilot studies to evaluate a drug called cyclosporine, which specifically affects the portions of the body's immune system believed to be responsible for mounting a misguided assault on the eye. The results of those small-scale studies are now in: Cyclosporine proved to be effective in protecting the vision of some patients with autoimmune uveitis. Now the NEI is recruiting more uveitis patients for a larger-scale trial of the drug. If this therapy is successful, the finding will be a milestone in the treatment of autoimmune disease as well as in the control of ocular inflammation.

Another landmark research effort is now underway to improve the treatment of patients with the most common form of glaucoma, called the chronic, open-angle type. One of the major problems in the treatment of glaucoma is that the drugs used to control intraocular pressure are not always effective. In addition, they can cause side effects which make it difficult for many people to adhere to the medication schedule prescribed by their doctor. Clearly, there is a great need to explore alternative methods of therapy. A promising treatment that has been under investigation in the last few years is argon laser trabeculoplasty, a procedure in which laser treatment is used to lower intraocular pressure by improving the outflow of fluid from the eye. A carefully controlled clinical trial to evaluate its use for treatment of newly diagnosed cases of open-angle glaucoma is now underway with NEI support. This clinical trial will evaluate the long-term effectiveness of the laser method and compare its usefulness to that of medications. The information gained should reveal the relative benefits of the two types of treatments and tell which glaucoma patients would be most likely to be helped by each type. We hope that, through the findings of this and other glaucoma research projects sponsored by the NEI, many more people can be spared visual loss from this eye disease, which is currently responsible for 12 percent of all new cases of blindness in this country.

I am pleased to report that we are also continuing our fight against another common cause of visual disability--diabetic retinopathy. As I have reported in earlier years, NEI scientists have been responsible for significant advances in our understanding of the mechanisms by which diabetes damages tissues in the eye and elsewhere in the body. In fact, a class of drugs developed at the NEI--drugs called the aldose reductase inhibitors--seem to have great potential for preventing diabetes-associated tissue damage. Research in this highly promising area has moved forward so rapidly that a clinical trial of an aldose reductase inhibitor is now underway. The objective is to determine whether treatment with this drug can delay or prevent the onset of diabetic retinopathy in insulin-dependent diabetics whose eyes are now healthy. We hope that this study, which is jointly sponsored by the NEI and the pharmaceutical firm Pfizer, Incorporated, will yield information that will be of great value to everyone concerned with improving the visual health of our Nation's diabetic population.

To better safeguard the visual health of another large group of Americans--the elderly--the National Eye Institute has initiated a clinical trial to explore means of preventing or slowing the progression of aging-related maculopathy. This very common retinal disease, also known as senile macular degeneration, can cause diminution or total loss of the central vision needed for reading and driving. Last year I reported new research results showing that laser treatment can benefit patients who are in the greatest danger of losing sight from this disease. Of course, it would be much better if we were to develop preventive measures that would keep people free of the disorder, or at least arrest it before it reaches a sight-threatening stage. The newly initiated NEI study is designed to take a significant step toward this goal by investigating whether nutritional therapy and special protective eyeglasses can slow or halt this disease. If this new treatment approach proves to be of value, eventually it may lead to a great reduction in the incidence of visual handicaps among older people.

All of the research projects that I have told you about thus far are designed to yield findings that will have almost immediate clinical applications. But the National Eye Institute is also concerned with more basic, long-term studies that will lay the groundwork for clinical advances in the next decade and even beyond. One of the most exciting involves the application of concepts and techniques from the fields of biochemistry and molecular biology to one of the most formidable unsolved problems facing ocular medicine today. That is the problem posed by genetic diseases that cause visual impairment. These conditions, which include the blinding retinal disorders called the retinitis pigmentosas and a host of other hereditary conditions, almost defied biochemical investigation for decades because of the unacceptably high risks involved in removing samples of the affected tissues from the living eye.

One of the most encouraging developments in the recent history of vision research is that investigators are finding ways around this obstacle and moving closer and closer to an understanding of the molecular mechanisms responsible for these blinding diseases. In past testimony, I have told you part of this story, how NEI investigators are using animal models of the human disease to explore the biochemical mechanisms responsible for retinal cell breakdown and thus take the first steps toward devising rational treatment approaches. I've also told you how scientists have used detailed studies of blood chemistry to discover the enzyme abnormality responsible for the hereditary blinding disease called gyrate atrophy, making this condition the first of the hereditary retinal degenerations to have its biochemical basis known, and the first to be treated with a specific therapy.

Now I would like to tell you about new studies that are utilizing gene probes and other tools drawn from molecular biology to get even closer to the root causes of these genetic disorders. One particularly promising series of investigations concerns retinoblastoma, a cancer that originates in the retina during early childhood and may claim the vision or even the life of its victims. National Eye Institute-supported grantees have been major contributors to a pioneering research effort which appears to have come very close to identifying the actual gene defects responsible for retinoblastoma. Methods have now been devised to examine genetic material drawn from cells outside the eye and determine whether the defective gene or its normal counterpart is present. Thus it is likely that there will soon be a way to tell whether a particular child is at risk for retinoblastoma, and that information will be obtained even before the slightest sign of abnormality is present in the eye. In the near future, we expect that this method will be used to screen families known to be at risk of retinoblastoma and identify those children who will need particularly close medical surveillance and early treatment of incipient tumors. But in the more distant future--perhaps 10 years from now--we hope that methods of compensating for the defects of flawed genes will have been developed, so that information of the sort we have now obtained can be used to devise an actual gene therapy for retinoblastoma. Then it may be possible to stop the disease process before it starts.

Investigators supported by the National Eye Institute are now gathering information needed to devise gene therapy for several other hereditary eye diseases as well. For example, studies are now underway to isolate and characterize the gene responsible for abnormal activity of an enzyme called phosphodiesterase, which is believed to play a key role in the onset of some of the retinitis pigmentosa-like diseases that occur in animals. Another team of scientists is searching for the gene that is responsible for the enzyme defect known to exist in gyrate atrophy. Other investigators are examining the genes that carry the information needed to make the light-sensitive proteins of the retinal cells, in hopes of discovering the genetic basis for congenital light-perception problems such as color deficiency. In addition, information is being rapidly acquired on the genes that govern the synthesis and assembly of the proteins of the lens; eventually, this knowledge may be applied to the prevention of cataract.

Molecular genetics opens up a whole new world of vision research for us, a world in which we will not have to accept certain genetic defects as givens and merely attempt to contain the damage they cause, but in which we will be able to manipulate the very structure of the genome to maintain normal function in spite of the accidents of heredity.

These molecular biological studies, like the studies of cyclosporine and autoimmune eye disease that I mentioned earlier, illustrate one of the prime strategies that the National Eye Institute is employing in its effort to combat blinding eye disease. That strategy is to encourage an exchange of concepts and methods between vision research and other rapidly advancing disciplines that seem to have much to contribute to the understanding and control of blinding eye disease. Molecular biology, immunology, and neurobiology are all being tapped in this way.

Another important strategy is one that I have spoken about in previous years. That is research planning. I am pleased to tell you that in the past year we have completed publication of a new multivolume report that is expected to serve as a guide for vision research over the next 5 years. This document, prepared with the advice of over 350 scientific consultants, identifies the highest-priority areas for future studies. It has been distributed to scientists and institutions nationwide and abroad. Dissemination of the plan is expected to increase the number of well-designed proposals addressing important and potentially solvable problems of visual science and lead to research results that will improve the visual health of Americans for generations to come. Mr. Chairman the request for the NEI for FY 1985 is $157,873,000 an increase of $3,194,000 over the comparable FY 1984 level. I would be happy to answer any of your questions.

# Biography of Dr. Carl Kupfer

Date & Place of Birth: February 9, 1928 - New York, New York

Citizenship: United States

Marital Status: Married

Education:

June 1945 - Graduated from High School
June 1948 - A.B., Yale University
June 1952 - M.D., The Johns Hopkins Medical School

Board Certification: American Board of Ophthalmology, 1958

Brief Chronology of Employment:

| | |
|---|---|
| 1952 - 1954 | Internship and Assistant Residency,<br>Wilmer Eye Institute<br>The Johns Hopkins Hospital |
| 1953 - 1954 | Laboratory Assistant, Biostatistics,<br>The Johns Hopkins School of Medicine |
| 1957 - 1958 | Research Fellow in Ophthalmology,<br>Wilmer Eye Institute<br>The Johns Hopkins Medical School<br>Laboratory Assistant, Biostatistics,<br>The Johns Hopkins Medical School |
| 1958 - 1960 | Research Fellow in Ophthalmology,<br>Harvard Medical School |
| 1960 - 1962 | Instructor in Ophthalmology,<br>Harvard Medical School |
| 1962 - 1966 | Assistant Professor of Ophthalmology<br>Harvard Medical School |
| 1966 - 1970 | Professor and Chairman in Ophthalmology,<br>University of Washington School of Medicine;<br>Research Affiliate, University of Washington<br>Primate Center |
| 1970 - | Director, National Eye Institute<br>National Institutes of Health |

Military Service:

United States Air Force, November 27, 1954 - November 26, 1956

Societies:

American Physiological Society
Association for Research in Vision and Ophthalmology
American Academy of Ophthalmology
American Ophthalmological Society
Pan American Ophthalmological Society

Honors and Other Special Scientific Recognition:

Henry Strong Denison Scholarship 1949-1950
Consultant to Blind Babies Home, Boston, Massachusetts, 1962-1966
Program Director, Ophthalmology Training Grant, Massachusetts Eye and Ear Infirmary, 1962-1966

Member, Vision Research Training Committee, National Institutes of Health, 1963-1964
Member, Neurology Program - Project B, National Institutes of Health, 1967-1969
Member, Advisory Committee of Basic and Clinical Research, National Society for the Prevention of Blindness, Inc., 1968-
Editorial Board, Investigative Ophthalmology, 1969-1977
Clinical Associate Professor, Howard University, Division of Ophthalmology, 1970-
Editorial Board, American Journal of Ophthalmology, 1971-
Member, Scientific Advisory Committee, Fight for Sight, 1971-
Member, Scientific Advisory Panel of Research to Prevent Blindness, 1971-1974
The Secretary's Special Citation, Department of Health, Education, and Welfare, April 1972
Sanford R. Gifford Memorial Lecture, May 1972
The Superior Service Award, Department of Health, Education, and Welfare, May 1974
Ticho Memorial Lecture, September 1974
Member, National Diabetes Advisory Board, 1976-
Migel Medal, American Foundation for the Blind, October 28, 1976
Edwin B. Dunphy Lecture, June 1977
Public Service Award in Ophthalmology, American Academy of Ophthalmology and Otolaryngology, October 1977
Speaker, Academy of Medicine of Washington, D.C., Winter Meeting 1980
Sixth Lorand V. Johnson Lecture, April 1980
Principal Speaker for Friends of Eye Research, Rehabilitation and Treatment at the Helen Keller Centennial Congress, June 25, 1980
C. Dwight Townes Memorial Lecture, March 1981
Speaker, Medical College of Wisconsin Eye Institute Resident Alumni Meeting, June 1981
Speaker, Symposium on Basic Aspects of Glaucoma Research, Anatomic-Institute, University of Erlangen-Nurnberg, Germany, September 1981
Speaker, 35th Annual Congress of Japanese Clinical Ophthalmology, Juntendo University School of Medicine, Tokyo, Japan, November 1981
Speaker, Glenn A. Fry Award Lecture, American Academy of Optometry, December 1981
Senior Executive Service Bonus, Department of Health and Human Services, 1981
Richard Stein Lecture, Maurice and Gabriella Goldschleger Eye Institute, Tel-Aviv University, Sackler School of Medicine, Israel, February 1982
Associate Examiner, American Board of Ophthalmology Oral Examinations, Philadelphia, Pennsylvania, April 1982
Johns Hopkins Society of Scholars, Johns Hopkins University, May 1982
Lecturer, Course in Community Eye Health, Institute of Ophthalmology, University of London, October 1982
Honorary Doctor of Science Degree, Scheie Eye Institute, University of Pennsylvania, November 1982
Member, Institute of Medicine, January 1983 - Present
Guest Speaker, Association of University Professors of Ophthalmology Annual Meeting, March 1983
Guest Lecturer, Louisiana State University, April 1983
Speaker, XIV Jules Stein Lecture, Los Angeles, California, April 1983
Recipient, Special Award of Honor, The Juvenile Diabetes Foundation, June 1983

Recipient, David Rumbough Memorial Scientific Award, The Juvenile Diabetes Foundation, June 1983
Guest Speaker, Suburban Hospital, Bethesda, Maryland, September 1983
Guest Speaker, Annual Board Meeting, Helen Keller International, New York, September 1983
Guest Speaker, Michigan Opthalmological Society, October 1983
Guest Speaker, Henry Ford Hospital, Detroit, Michigan, October 1983
Guest Speaker, Juvenile Diabetes Foundation, Bethesda, Maryland October 1983
Guest Speaker, Kingsbrook Jewish Medical Center, Brooklyn, New York, December 1983
Recipient, Presidential Rank Award of Meritorious Executives, 1983

International Appointments:

Member, Board of Trustees, Helen Keller International Incorporated, 1975-
Chairman, Projects and Priorities Committee, International Agency for the Prevention of Blindness (IAPB), 1975-1982
Coordinator for USA, US-Japan Collaborative Agreement in Vision Research, 1976-1982
Organizer, Oxford Assembly, IAPB, 1978
Member, International Vitamin A Consultative Group (IVACG), WHO 1973-
Visiting Professor, Pan American Ophthalmological Association, October 1975
Member of US Delegation to World Health Assembly, May 1978
Member, Advisory Group for Prevention of Blindness Programme, WHO, 1978-
Consultant, Pan American Health Organization (PAHO), 1978-
Temporary Adviser, WHO Task Force on Data on Blindness Meeting, Geneva, November 1978
Participant, Meeting on the Role and Functions of the National Institutes of Ophthalmology, Brussels, December 1978
Coordinator for USA, Priority Area "Eye Diseases," US-USSR Program for Health Cooperation, 1978-1981
Member, WHO Expert Advisory Panel on Trachoma and Prevention of Blindness, 1979-1984
Short-Term Consultant to Regional Office for South East Asia, WHO, New Delhi, India, December 1979-January 1980. Assignment to evaluate the Indian Plan for the prevention and control of blindness and to advise on training and research activities.
Consultant to WHO for Defining Guidelines for Blindness Prevention Programs in Africa, Bamako, February 24-27, 1980
Speaker, General Assembly of the World Council for the Welfare of the Blind, Antwerp, August 1979
Director, WHO Collaborating Center for the Prevention of Blindness, National Eye Institute, Bethesda, MD, 1979-
President, International Agency for the Prevention of Blindness, October 1982-Present

### INTRODUCTION OF ASSOCIATE

Dr. KUPFER. Mr. Chairman, to my left is Mr Edward McManus, who is the Deputy Director of the National Eye Institute.

### PROGRAM PLANNING

Mr. Chairman, some 11 million Americans suffer some degree of visual impairment and half a million are blind. The aim of research supported by the National Eye Institute is to reduce this tragic burden of visual loss by improving the prevention, diagnosis, and treatment of a vast array of sight-threatening disorders that continue to claim new victims each year.

One of the prime strategies to achieve this goal is research planning, and we have just completed this multivolume national vision research plan covering the years of 1983 to 1987. This document, which has been distributed nationwide, will serve as a guide for the vision researcher to the priorities of the National Eye Institute.

We are now concerned with the implementation of this plan—and I'd like to give you one or two examples of how our planning process has already led to projects which have borne fruit.

### LASER TREATMENT

Last year we discussed the successful conclusion of a clinical trial which showed that laser photocoagulation is beneficial in reducing by over 50 percent the cases of blindness resulting from a certain type of macular degeneration.

We have continued to look at the value of laser photocoagulation in other conditions and have this year completed a clinical trial which showed that this treatment is effective against histoplasmosis infection of the retina. This is a fungal condition which causes a significant amount of blindness among young people in the East Central and Midwestern United States. We have found that use of the laser will reduce by more than 50 percent the incidence of blindness resulting from this condition.

### DIABETIC RETINOPATHY

These are the accomplishments that have resulted from our planning process which identifies high priority research areas that should be pursued. But there is another area which the plan has dealt with and with which we are just coming to grips. We have reported on occasion here the treatment of diabetic retinopathy. And as you will recall, several years ago we found that photocoagulation will reduce the rate of blindness in people who have already developed diabetic retinopathy. But what we ultimately want to do is to prevent the development of diabetic retinopathy. The scientists in our intramural program have been looking at the metabolism of the retina in diabetes and galactosemia, another disease in which sugar metabolism is defective. They have found that there is an enzyme, called aldose reductase, which triggers the changes that lead to diabetic retinopathy. We have been working very hard to develop inhibitors of this enzyme and through the cooperation of the Pfizer laboratories have identified a potent aldose reductase inhibitor called Sorbinil. Just recently we have begun a nationwide clinical trial in collaboration with Pfizer to try to prevent the development of diabetic retinopathy in insulin-dependent juvenile diabetics. I think this might be one of the most exciting clinical trials that we have undertaken.

## AGE-RELATED EYE DISEASES

I would not want to give the impression that we have solved all the eye problems that face us. Most of the major eye problems in this country are aging related. In the next 50 years, we are going to see an increase of 100 percent in the American population over the age of 55 and a 150-percent increase in the population over the age of 85. So we will be increasingly confronted with diseases that are aging related, such as cataract, glaucoma, and others.

In addition, I think we must not lose sight of the fact that we also have a large population of young people and that there is a significant amount of basic research that must be used to approach the types of diseases that affect young people, such as retinitis pigmentosa and other hereditary and developmental conditions.

## GENETIC RESEARCH

To find out how to prevent these, we've got to turn to the laboratory and call upon the most sophisticated biochemical and molecular genetic techniques to study these diseases.

One of the most encouraging developments in the recent history of vision research is that investigators are moving closer to understanding the molecular mechanisms responsible for once hopeless genetic diseases. To do this they are utilizing gene probes and other tools drawn from molecular biology to get at the root causes of these genetic disorders.

One particularly promising series of investigations concerns retinoblastoma, a cancer that originates in the retina during early childhood and may claim the vision or even the life of its victims. National Eye Institute supported grantees have been major contributors to a pioneering research effort which appears to have come very close to identifying the actual genetic defects responsible for this cancer. Studies are now under way to gather similar information on the genes that are responsible for certain forms of retinitis pigmentosa and on those which govern the process by which cataracts are formed.

Molecular genetics opens up a whole new world of vision research for us, a world in which we will not have to accept certain genetic defects as given and merely attempt to minimize the damage they cause, but in which we will be able to manipulate the very structure of the genome to maintain normal function in spite of the accidents of heredity.

### BUDGET REQUEST

Mr. Chairman, the request for the National Eye Institute for fiscal year 1985 is $157,873,000, an increase of $3,194,000 over comparable 1984.

I would be happy to answer any questions.

### NEI PRIORITIES

Senator WEICKER. I have a couple of questions for response to the record, but two questions, first of all.

What are the first two priorities in your research? You say you list the priorities. What are one and two?

Dr. KUPFER. Well, sir, I would have to respond to that by saying we have five programs. We're dealing with retinal diseases, cataracts, glaucoma, corneal disease, and diseases of the visual sensorimotor system. We really have to look at the top priorities in each of these, but if I had to generalize, I would say our two top priorities are one, to develop the research base in molecular biology and molecular genetics, and to begin to approach the blinding genetic diseases of the young.

And the second would be the rapid application of what we learn in the laboratory to try to affect either prevention or treatment of diseases.

### BUDGET IMPACT

Senator WEICKER. And on what aspect of your activities does the administration budget impact most harshly?

Dr. KUPFER. Well, sir, we have for at least 10 years put the bulk of our budget into investigator-initated research grants; 93 or 94 percent of our research grant dollars are in that category, so it is very difficult for us to draw funds from other mechanisms to support what we have always considered the main element of fostering progress in research.

So that I would say that any action that reduces the number of research grants and the number of scientists that we can bring into studying these vision research problems would be a very serious problem, indeed. We are in a growth phase. We are sort of in puberty, if you will. We're 13 years old—14 years old—and I think that we still have to have additional growth if our potential is to be fully realized. So any reduction in this growth curve will cause a problem.

I think the second problem is we, being a new institute, have looked to moving into the NIH ambulatory care research facility [ACRF] with great anticipation, but we now find that we will not be fully able to take advantage of this new facility. While we as an individual Institute are not fiscally constrained, the NIH as a whole needs to have sufficient resources in order to fully utilize the ambulatory care research facility. We at the NEI and at NIH have a very, very significant opportunity to apply our research knowledge to clinical problems, and I would not like to see that hampered.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. There will be additional committee questions which will be submitted for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

### BUDGET FORMULATION

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: The National Eye Institute (NEI) was provided wide latitude in formulation of its budget. Initially in the budget development process, the Director of the National Institutes of Health (NIH) asks each Institute to provide their professional judgment estimate of what is required for their program. A formal review meeting is then held with the Director of the NIH who modifies this request to the extent required by his scientific judgment and the technical restrictions he may be operating under.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: The budget request will allow the NEI to maintain the current momentum in its scientific program.

### RESEARCH PROJECT GRANT LEVELS

Question: To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer: There would be a reduction of 1.7 percent in the funding level of noncompeting research project grants in FY 1985. Competing renewal and new grants would be reduced or 3.9 percent below projected levels. Even at these reduced levels the most important research would be supported. Progress on specific projects might be slower than originally planned, but no projects would be eliminated, or delayed.

### CORE AND CENTER GRANTS

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84?

Answer: The FY 1985 NEI request includes sufficient funds to support the same number of core and specialized clinical research center grants as in FY 1984.

Question: What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: We expect to be able to continue our efforts to translate the results of basic research into prevention and treatment.

## RESEARCH TRAINING

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: The FY 1985 budget represents a decrease of $359,000 and 27 full-time training positions. Our level of support for research training has been decreasing over the last five years. My chief concern at this point is that young, new, scientists who are considering a career in research may view this trend as indicating a lack of commitment to research training in particular and to all of our research programs. I fear that talented individuals may decide to forego a career in biomedical research because they do not believe their initial investment of time and energy will place them in a position to obtain funding, even after they have completed the training phase of their careers and become ready to do independent work.

## 1985 CURRENT SERVICES

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: An additional $5.4 ($5,385,000) million would be required to continue Institute programs at the 1984 level.

## FTES

Question: The Budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Answer: The FTE reduction of 588 proposes a loss of 9 FTEs for the NEI. These reductions will be taken primarily in the other than full-time employment category. It is difficult to assess the precise impact this reduction will have on our programs. The Institute will attempt to implement the reduction in a way that minimizes the impact on research in progress and on the effective management of our organization.

## AIDS RESEARCH

Question: Many victims of AIDS, as we understand it, suffer from viral infections of the retina. What research are you doing on this aspect of AIDS -- and what are your funding levels for FY 1984 and FY 1985?

Answer: Patients with AIDS are susceptible to cytomegalovirus (CMV) retinitis--an infection of the retina with a common virus which can cause severe infections threatening the eye or other organs when the body's immune defense system is weakened by disease or immunosuppressive drugs. NEI-supported investigators have found that the AIDS patients with CMV retinal infection are the ones who are at greatest risk of dying within a few months, apparently because they are in a very severely immunosuppressed state.

NEI investigators at the NIH Clinical Center have been studying AIDS patients for characteristics that might indicate which of them are at greatest risk of developing CMV retinitis. In a study of some 50 AIDS patients, they have found that the individuals with a low count of certain types of white blood cells (inducer T lymphocytes) are the most likely to develop the retinal infection. In another study, they have obtained some evidence indicating that the CMV retinitis may develop in a sequence of stages which can be monitored. The funding levels for these intramural projects are $58,000 in FY 1984 and $61,000 in FY 1985.

The grant-supported studies now in progress are not supported by a block of funds designated exclusively for AIDS research; thus, the NEI does not have a specific funding level for extramural research related to AIDS. Instead, NEI scientists, and eye investigators throughout the country, are taking advantage of opportunities to do collaborative research with immunologists, cancer specialists, and infectious diseases experts at the NIH Clinical Center and other medical centers where many AIDS victims are being seen.

Question: What progress do you anticipate making against vision problems brought on by AIDS?

Answer: NEI intramural scientists are cooperating with medical investigators from other NIH institutes in studies of various aggressive pharmacological therapies which might prolong, or even save, the lives of AIDS victims. In these studies, the extent of AIDS-related abnormalities detectable in the patients' eyes will be used as one indicator of the progression and severity of the overall disease. It is anticipated that reversals of the ocular manifestations of the disease will provide a prognostic indicator for preservation of life.

From the research now being conducted with AIDS victims, we hope to gain some additional information which might eventually benefit other types of immunologically vulnerable patients suffering from eye infections. These might include infants with ocular herpes virus infections, cancer patients who have developed ocular infections as a result of immunosuppressive therapy, and transplant patients.

## HERPES RESEARCH

Question: What research progress are you making in the area of protecting the eye from damage by the herpes simplex virus?

Answer: For years, NEI-supported investigators have been in the vanguard of research on herpes. Several of the best anti-herpes agents now available to the practicing physician, including the medication which has now become the favored treatment for herpetic meningitis, were developed by eye researchers. The search for better anti-viral agents to use against herpes in general, and ocular herpes in particular, is continuing. NEI-supported investigators are attempting to find compounds which will more effectively prevent the herpes virus from reproducing in ocular tissues but will not harm normal, uninfected cells in those tissues.

Question: Are any useful antiviral drugs on the horizon?

Answer: Among the promising agents that are undergoing animal testing at this time are 2'fluoro-5-methyl-ara-uracil (FMAU) and

2'fluoro-5-iodo-ara-C (FIAC). Also, scientists supported by the NEI are investigating agents that may prevent ocular herpes from recurring. To achieve this it will be necessary to find a way to keep herpes virus which is lying dormant in the nerves near the eye from becoming reactivated and causing another flare-up of ocular disease. Recent research performed on herpes-infected nerve tissue in laboratory culture has shown that reproduction and release (shedding) of the virus can be inhibited by incubating the tissue in a mixture of monoclonal antibodies which are designed to attach themselves to specific viral proteins. If this approach to blocking the re-emergence of latent virus works in living animals, the procedure may offer a way of preventing recurrent attacks of herpes in humans.

## BIOTECHNOLOGY & FACILITIES

Question: We hear much discussion about the need for new or modernized facilities in the biomedical research field. How significant is the problem of inadequate facilities in the vision research field?

Answer: Updated and modernized vision research facilities are needed in order for us to take advantage of the scientific opportunities that are now emerging. Some of the equipment in our research laboratories is ten or more years old and is worn-out or obsolete. Furthermore, the great technological advances of the past few years have led to the development of expensive, specialized, and very powerful new instruments that must be acquired and properly housed so they can be made available to vision researchers. Therefore, our resource needs have broadened to include this equipment as well as the laboratory facilities it is placed in. The National Advisory Eye Council has passed a resolution that these needs should indeed be addressed, but not until we are able to fund approximately 50 percent of our approved grants.

Question: In the past this Subcommittee has provided several millions of dollars for the development of vision research facilities. How was this money used, and is any of it still unspent?

Answer: Three million dollars were appropriated in FY 1980 and $2 million were provided in FY 1982 for grants to improve vision research facilities. The NEI has spent the $5 million, for 14 "construction" grants to the institutions shown below. In some cases existing facilities were renovated to make them more appropriate for the vision science programs which would be housed there. Other grant awards provided partial support for construction of additional or new space where vision research would be conducted.

University of Miami
University of Michigan
University of Missouri
University of Illinois
Estelle Doheny Eye Foundation
Boston University
University of Rochester
Johns Hopkins University
New England Medical Center

Medical College of Wisconsin
Emory University
Rockefeller University
University of California
Oakland University

## LASER TREATMENT FOR GLAUCOMA AND RETINAL DISEASES

Question: The Subcommittee is interested in the degree to which lasers are used in treatment of glaucoma and degenerative diseases of the retina. How widespread is the use of lasers in treatment of eye diseases?

Answer: Nationwide clinical trials supported by the NEI have demonstrated the safety and effectiveness of laser photocoagulation as a treatment for several retinal diseases. These include: 1) diabetic retinopathy; 2) one form of aging-related (senile) macular degeneration; and 3) ocular histoplasmosis, an infectious disorder endemic to the midwestern United States. Because of these studies, use of this treatment has become more common, and today there are as many as 4,000 lasers being used by United States ophthalmologists to treat people who are at risk of losing their vision from these retinal disorders.

To gain more knowledge that can be used to prevent blindness from retinal disease, the NEI is now supporting additional clinical trials involving laser treatment. For example, the Early Treatment Diabetic Retinopathy Study (ETDRS), will determine whether laser treatment might yield even better results if it is used earlier in the course of diabetic retinopathy, before the patient reaches the advanced stage of the disease where the risk of blindness is greatest. Twenty-three medical centers around the country are participating in the study. If it finds that earlier laser treatment is beneficial, use of the procedure may become even more widespread.

In the Macular Photocoagulation Study, twelve medical centers are participating in a clinical trial of a new laser--the krypton laser--to see if it can be used to preserve vision in patients who have aging-related macular degeneration that has already invaded the area near the fovea--the highly sensitive center of the retina which provides the fine vision used for reading. If the krypton laser proves to be of value in this trial, that finding would result in laser treatment's being extended to some macular degeneration patients who are not currently being considered for laser therapy.

Laser therapy is also being used to treat two types of glaucoma. One is angle-closure glaucoma, a disorder which has long been treated primarily by surgery. In the past few years laser iridotomy, which creates a small hole in the iris to relieve pressure build-up in the eye, has almost completely replaced the surgical procedure iridectomy to treat angle-closure glaucoma. In contrast to iridectomy, the laser treatment is a noninvasive outpatient procedure which may inconvenience a patient for only part of a day, after which he or she may resume routine activities. But like iridectomy, the laser procedure can permanently lower intraocular pressure and prevent loss of vision in affected eyes.

The other type of glaucoma now being treated with the laser is open-angle glaucoma, the most common form of the disease and the leading cause of severe visual loss in the United States. Argon laser trabeculoplasty has become an acceptable alternative to surgery in treatment of severe open-angle glaucoma and in patients who cannot tolerate anti-glaucoma medications. There are indications that in these severe cases the laser treatment, which helps to open the drainage pathways by which aqueous humor leaves the eye, thereby lowering intraocular pressure, can reduce or eliminate the need for the medications that many patients must take on a lifelong basis. The NEI is now sponsoring a multicenter controlled clinical trial to determine the value of laser trabeculoplasty compared to continuing medication in the treatment of newly diagnosed open-angle glaucoma. If the laser treatment is found to offer advantages over conventional drug treatment for many patients with recently diagnosed glaucoma, this finding would also be likely to stimulate increased use of the laser nationwide.

## EFFECTS OF LASER THERAPY

Question: Lasers may have advantages over other methods of treatment, but can they have undesirable effects in an area as sensitive as the eye is?

Answer: Like other methods used to treat eye diseases, the various laser procedures can have undesirable side-effects, and these are carefully weighed against the possible benefits by medical scientists participating in NEI-supported clinical trials and by practicing ophthalmologists as well. With respect to laser treatment of the highly sensitive retina, we are certainly concerned about undesirable effects, for the laser is used, essentially, to contain --or "spot weld"--damaged areas with the beam of laser energy. For example, the goal in treatment of aging-related macular degeneration is to stop the spread of macular disease and preserve the center of sight, the fovea. However, if the disease is too close to the fovea, the laser treatment may be more harmful than beneficial. This is why National Eye Institute investigators are evaluating new forms of laser energy to see if we can develop a method of treating macular degeneration and possibly other retinal diseases which does maximal good with minimal damage. The fact remains, however, that the laser treatments now in widespread use for various retinal diseases have been evaluated in clinical trials and shown to have more benefits than risks, on balance.

In the case of laser treatments for glaucoma, no serious side-effects have been reported for the laser iridotomy procedure used to treat the angle-closure form of the disease. However, argon laser trabeculoplasty treatment for open-angle glaucoma is occasionally followed by a sharp rise in intraocular pressure, which requires prompt medical treatment. More commonly, small, transient pressure rises have been noted; these apparently cause no lasting harm. Because this laser trabeculoplasty procedure has been used for only a few years, it is not yet possible to state what its long-term success rates will be for use at various stages of open-angle glaucoma, nor has it been determined which types of glaucoma patients will best be served by this procedure in preference to drugs or conventional surgery. The current NEI-supported clinical trial and other studies should provide answers to these questions.

## RESEARCH PLAN IMPLEMENTATION

Question: The periodic vision research plans lay out your priorities for a number of years into the future and become a guide for the development of Eye Institute programs. What action are you taking on the priorities that were spelled out in the 1983-87 vision research plan?

Answer: Because in its support of research, the NEI strongly emphasizes the individual, investigator-initiated, research project grant, implementation of the plan's priorities depends in great part upon scientists voluntarily submitting high quality grant applications for research in priority areas. For this reason, the Institute has distributed the Plan widely among the scientific community to ensure that program goals and priorities are well known.

Over 3,000 copies of various sections of the Plan were distributed during the past year to scientists working in vision research. An additional 4,000 copies were mailed in response to requests for the Plan which resulted from announcements of its availability in scientific journals and newsletters. Also, NEI staff members distributed the Plan at major scientific meetings, where they presented exhibits and gave speeches featuring the Plan's recommendations.

In addition, the following activities, intended to implement specific sections of the Plan, are scheduled for FY 1984-1985.

- Workshops will be held on the following:
  - Molecular genetics approaches to the study of the retina and inherited retinal degenerations.
  - Establishment of eye donor programs for obtaining tissues from eyes with glaucoma for laboratory research.
  - Vision screening of infants and preverbal children.
- A conference is planned to determine the state of knowledge about the tear glands and their fluids in health and disease and to foster the development of new basic and clinical research grant applications in this area.
- Requests for Applications will be issued for research on the assessment of visual function in low-vision patients.
- Program Announcements will be issued to encourage the submission of grants for research on:
  - Influences of nutritional and environmental factors on retinal cell function and degeneration.
  - Ocular immunology.
  - Vergence eye movements (those in which the two eyes move in opposite directions to look at an object). Although disorders of vergence may affect as much as a fourth of the United States population, relatively little research has been conducted in this important area.

- o Molecular research in strabismus, amblyopia, and visual processing.

Question: How does your budget request reflect -- or not reflect -- the current vision research plan?

Answer: The plan, prepared by the National Advisory Eye Council, calls for $225 million for FY 1985 to take full advantage of all research opportunities identified to be funded under optimal budget conditions. Our budget request for this year is $157 million.

### PROGRAM IMPACT OF BUDGET REQUEST

Question: What won't get done if we approve your budget request as you submitted it?

Answer: The amount of our request will allow us to take advantage of the very best opportunities to support high quality research in most of the areas of the plan designated as having high priority. However, it will be necessary to postpone certain targeted research activities, in particular certain clinical trials, until a later time. Examples of trials that may have to be put off until another year are treatment of ocular melanoma, alternative treatments for retinal detachment, cryotherapy for acute retrolental fibroplasia, and steroid treatment of optic neuropathy due to Grave's disease.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### COLLABORATION WITH PRIVATE SECTOR

Question: Dr. Kupfer, in your prepared opening statement you refer to a clinical trial of a drug used in treating a diabetic disorder of the eye -- a trial that is jointly sponsored by the Institute and Pfizer, Incorporated. Is this sort of jointly sponsored research common at the Eye Institute?

Answer: Public-private collaborative studies of this magnitude have not been common in the history of the NEI because they are dependent upon new drug development with commercial potential for treating eye disease. This is, of course, a rare event. In addition to the example you mention, however, there has been at least one other occasion on which this combination of circumstances has occurred and resulted in a major, jointly sponsored research effort. I am referring to the study that is evaluating a new immunosuppressive drug, cyclosporine (Sandimmun)--produced by Sandoz, Inc.--in the treatment of uveitis, a leading cause of visual impairment in the United States. This also is a multimillion dollar, jointly sponsored research project whose development has been facilitated because both the NEI and the pharmaceutical firm have recognized that it is in their best interests to pool technical know-how and resources to conduct a clinical trial.

In addition, the NEI is collaborating with two other drug companies to support promising research in cataract and diabetic retinopathy. In these instances, the private investment is small in relation to the Federal, but is providing a much-needed boost in support of training--an area where NEI fiscal capabilities are minimal.

Question: Can you give us a rough idea of the amount the private sector is spending on jointly sponsored Eye Institute research?

Answer: The private sector is contributing about $3,000,000 annually to jointly sponsored research with the NEI.

Question: Last year you estimated you would spend $457,000 on rent, communications and utilities in fiscal year 1984. Your current estimate has gone up to $533,000. Why did you initially underestimate these costs by $76,000?

Answer: Our estimates for rent, communications and utilities costs in 1984 were increased to reflect our actual expenditures in 1983, which were more than originally planned. There were two main reasons for the higher costs. Telephone and other communications costs increased as a result of the AT&T divestiture and the Institute has found that it is more economical to lease than to purchase some of our office equipment.

## NEI VS. NIH AWARD RATES

Question: Dr. Kupfer, in 1982, the latest year for which we have statistics, the award rate for the National Eye Institute was 48.4 percent, almost 10 percent greater than any of the other Institutes. Does this indicate that the Eye Institute is being treated more generously or is there some unique approach to the grant process of the Eye Institute that produces this result?

Answer: The answer is that the difference in funding rates reflects a unique approach, which dates back to the creation of the National Eye Institute. From the beginning, the NEI management staff and the National Advisory Eye Council have been determined to build a research program that would be flexible enough to respond to the fresh scientific insights and new research opportunities that appear each year. Also, we have been conscious of the need to make our program as cost-effective as possible. In our opinion, the best way of achieving these goals is to channel as high a proportion as possible of the monies the NEI has available for extramural research into R01, individual research project grants (RPGs). These RPGs are initiated by individual investigators, have to compete again for funding every three years or so, and cost only about one-sixth as much as the large, multi-project (P01) grants that are utilized by some other components of the National Institutes of Health. The NEI does not fund program projects (P01). Through preferential use of RPGs as a funding mechanism, we assure ourselves of having the flexibility to select and support the highest possible number of meritorious scientific proposals with the funds that become available each year.

It is only because 89 percent of the NEI budget--as compared with 72 percent for NIH as a whole--goes for RPGs, and none of our budget goes for P01s, that we are in a position to fund a higher percentage of grant proposals than other Institutes. The following analysis will demonstrate this: For 1985 we expect to be awarding funds to support 38 percent of competing RPGs, as compared to an award rate of 30 percent for the NIH as a whole. But if NEI were to distribute its funds between RPGs and other award mechanisms, such as contracts, centers and program projects, placing the same emphasis on the latter as does the National Institutes of Health as a whole, we would anticipate that our 1985 award rate for competing research grants would be only 28 percent--about the same as the NIH-wide average.

Of course, we realize that each component of the NIH faces a unique set of research opportunities and needs, and must build its program around the funding mechanisms best calculated to address those variables. Thus we would not want to put our choices forward as an indication of what mechanisms the other Institutes should select, but rather as an example of the way in which a particular Institute can utilize the administrative flexibility made possible by the existence of different funding mechanisms to make choices that will maximize utilization of limited resources while supporting high-quality research.

## NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

**STATEMENT DR. DAVID P. RALL, DIRECTOR**

**ACCOMPANIED BY:**

**DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**JACK M. RIGSBY, BUDGET OFFICER**

**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. Next we'll hear from the National Institute of Environmental Health Sciences. The Institute is responsible for improving our understanding of how toxic agents in the environment may cause human disease. The Institute's budget request is almost $184 million or about $4 million above the fiscal 1984 funding level.

The lead witness for the Institute is Dr. David Rall, the Director, who last year provided us with an excellent explanation of the dangers to the water supply from careless dumping of toxic chemicals. And Dr. Rall, we're pleased to have you back.

[The statement follows:]

## STATEMENT OF DR. DAVID P. RALL

Mr. Chairman and Members of the Committee, I am pleased to be with you today to describe some of the research supported by the National Institute of Environmental Health Sciences (NIEHS). Established in 1966, NIEHS is the NIH Institute concerned with improving our understanding of how environmental agents cause human disease. Rather than focusing on any specific disease, NIEHS explores how the environment may cause human illnesses. This research is conducted primarily through grants and contracts to institutions throughout the Nation, and also by staff scientists in NIEHS laboratories in the Research Triangle Park, North Carolina.

Progress in biomedical research, coupled with improved health care and public health measures such as modern sanitation, has decreased substantially the threat from infectious diseases such as pneumonia, tuberculosis, and influenza which formerly made early death so familiar. Unfortunately, this decrease has been offset by an increase in chronic diseases, some of which are consequences of hazardous chemicals in the environment.

Therefore, NIEHS research seeks to better understand how environmental agents enter the human body and initiate adverse biologic reactions that may lead to disease and death. One key in this process is to identify chemicals or other agents for further research and practical environmental control. I will describe some of these research efforts undertaken by NIEHS through contracts, grants, or in our own laboratories.

Dioxin--specifically, 2,3,7,8-tetrachlorodibenzo-p-dioxin, or TCDD--is a toxic contaminant in 2,4,5-T and certain waste oils. NIEHS has been in the forefront of biochemical and toxicological studies of TCDD, beginning with the discovery several years ago that the TCDD-contaminated pesticide 2,4,5-T was teratogenic to rodents. Recent NIEHS-supported research has enhanced our understanding of the mechanism by which TCDD acts in the cell to produce its toxic effects. Scientists at, or supported by, NIEHS have published about 200 articles about dioxins in scientific journals.

NIEHS-supported scientists at the University of Wisconsin have characterized a mechanism by which TCDD (and related halogenated aromatic chemicals such as dibenzofurans and PCBs) acts at the cellular level. This work has led to the discovery of a particular receptor molecule within the cell that binds TCDD and related compounds. After this binding occurs, the chemistry of the cell is altered, apparently initiating the events which cause the various toxic effects seen in laboratory animals. This research should help us to more fully understand the TCDD receptor and how this interaction influences the range of toxicities of the different isomers demonstrated in laboratory studies. These basic research findings also allow us to understand the potential health consequences from human exposures to TCDD, and should assist other Government agencies with regulatory responsibilities to make risk estimates.

Scientists at the University of Rochester are determining how TCDD causes weight loss in laboratory animals. By examining different routes of administration, the weight loss seems to be due to TCDD's blocking absorption of nutrients in the digestive tract. Other effects of TCDD exposure such as liver dysfunction occur by any route. These results help us to predict possible consequences in humans that may depend on the route of exposure to dioxins.

A more applied TCDD study was conducted by the National Toxicology Program (NTP) at the request of the Environmental Protection Agency (EPA). A critical scientific issue for estimating the potential risk to the public from TCDD-contaminated soil is whether this toxic dioxin is bioavailable--that is, can be absorbed from the gastrointestinal tract. Until now many scientists have assumed that TCDD binds to soil and therefore the hazard should be relatively low in areas where soil is contaminated.

Using soil collected by EPA from Times Beach and the nearby Minker site, NIEHS scientists fed TCDD-contaminated soil by stomach tube to guinea pigs. Toxic effects were similar to those seen in guinea pigs receiving oral doses of pure TCDD and indicate significant TCDD absorption. Rats given this soil showed a 40-fold increase in the production of a liver detoxication enzyme, indicating that TCDD is absorbed from contaminated soil and produces the same biological changes that are seen when pure TCDD is administered orally. These data have practical application since people, especially children, may ingest contaminated dirt from hands, foods, and other sources as well.

Scientists at the Harvard School of Public Health are investigating the possible relationship between air pollution and various health effects, particularly from exposure to particulates (total suspended particulates, TSP) and sulfur dioxide ($SO_2$). This study involves monitoring the respiratory function of 9,000 adults and 12,000 first and second grade school children in each of six cities: two where air quality is below Clean Air Act standards for $SO_2$ and TSP, two which meet the Federal standard, and two which exceed it.

Indoor air quality is also being studied. Obvious factors such as air conditioning and heating types, cooking fuel, and passive smoking in the home will be compared with diseases such as asthma and bronchitis in children; the effects of smoking and occupation on adults will be correlated with these illnesses.

The National Toxicology Program (NTP) develops and evaluates scientific information about potentially toxic and hazardous chemicals. By bringing together the relevant programs, staff, and resources from the Public Health Service, DHHS, the NTP has centralized and strengthened activities relating to toxicology research, testing and test development efforts, and the dissemination of toxicological information. The NIEHS' Toxicology Research and Testing Program is the National Institutes of Health's portion of the NTP and supports about 85% of these national activities. The NTP tests chemicals in experimental animals for their potential to cause cancer, fetal abnormalities, effects on fertility and reproduction, immune system disorders, and other toxic effects. This is central to NIEHS' role in disease prevention. Equally important, the NTP is working to improve current research and testing methods.

Test systems must be developed to provide precise information more quickly and economically. Insight into how chemicals cause various effects is another goal. Thus, test methods development is an important responsibility of the Program, and includes investigation of short-term in vivo tests to detect chemicals which may cause liver, urinary bladder, and skin cancers. In vitro tests are being studied that should provide knowledge into the mechanisms of genetic toxicology and carcinogenesis.

Developing test systems which utilize state-of-the-art fundamental knowledge sometimes yields benefits that are broadly applicable to problems of human disease. This is illustrated by some findings that turned up in studies of the incidence of heritable mutations in mice. Surveillance of an untreated control group revealed a spontaneous mutation in an untreated control group that corresponds to the genetic disease in humans known as beta-thalassemia, or Cooley's anemia. In both the human and the mouse disease, the heritable anemia is due to a failure of the gene that directs the synthesis of the major beta-globin to produce the normal complement of hemoglobin. The importance of finding the mouse beta-thalassemia, and in defining its specific genetic cause, lies in providing an animal model for gene replacement therapy that may be applicable to humans.

The NTP has expanded the traditional two-year carcinogenesis test into a comprehensive toxicology study which will continue to provide definitive information on the chemicals' potential to cause cancer in experimental animals, but also will allow evaluation of genetic toxicity, chemical disposition, major organ toxicity, and effects on fertility and reproduction. This comprehensive approach to toxicology permits other agencies to make decisions to protect the public health.

Another activity I have discussed with other Committees of Congress developed from a problem of poor record keeping that the NTP encountered at a contract laboratory, Gulf South Research Institute. To better guarantee the integrity of experimental data from long-term studies collected at contract laboratories, we have initiated a more comprehensive data audit process. We have found that this is not a generalized problem among our contract laboratories. Experimental data from NTP-supported studies are being examined prior to release of draft technical reports for peer review or for distribution to interested parties. Since October 1983, NTP Technical Reports on toxicology and carcinogenicity studies have included audit findings. We have intensified our quality assurance procedures; and we are reviewing current methods of monitoring contracts with the objective of more stringent on-site assessment during the live animal phase of the studies.

As examples of recent results, the NTP's Board of Scientific Counselors approved the interpretations of three carcinogenesis studies. Benzene, a large volume solvent also used to make plastics, rubber, nylon, resins, and detergents, and a gasoline additive, is ubiquitous in our environment. Although long known to be a human carcinogen based upon epidemiological evidence, the

NTP studies provide information that should be useful to regulatory agencies considering establishing permissible exposure levels. The demonstration that 1,3-butadiene is carcinogenic is equally important because of the large numbers of workers in the rubber industry who are potentially exposed. The good news is that ascorbic acid or vitamin C did not induce any carcinogenic response after feeding this chemical in the diet to rodents.

Our budget request for Fiscal Year 1985 is $183,755,000, which represents an increase of $3,953,000 over the comparable 1984 level. I would be happy to answer your questions.

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## Biography of Dr. David P. Rall

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| Birthplace and Date: | Aurora, Illinois; August 3, 1926 |
| Marital Status: | Married; two children |
| Education: | Public Schools, Naperville, Illinois<br>B.S., North Central College, Naperville (1946)<br>M.S. (Pharmacology), Northwestern University (1948)<br>Ph.D. (Pharmacology), Northwestern University (1951)<br>M.D., Northwestern University School of Medicine (1951) |
| Professional Training: | Internship; Second (Cornell) Medical Division, Bellevue Hospital, 1952-53 |
| Experience: | Director, National Institute of Environmental Health Sciences, NIH, 1971-present<br>Director, National Toxicology Program, 1978-present<br>Assistant Surgeon General, USPHS, 1971-present<br>Associate Scientific Director for Experimental Therapeutics, National Cancer Institute, 1966-71<br>Medical Director, USPHS, 1963-71<br>Chief, Laboratory of Chemical Pharmacology, National Cancer Institute, 1963-69<br>Senior Surgeon, USPHS, 1959-69<br>Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute, 1958-63<br>Surgeon, USPHS, 1955-59<br>Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute, 1953-55<br>Research Associate in Pharmacology, Northwestern University, 1950<br>Assistant in Pharmacology, Northwestern University, 1949-50<br>Baxter Fellow in Pharmacology, Northwestern University, 1947-49 |

Association Memberships:

American Association for the Advancement of Science
American Association for Cancer Research
American Public Health Association
American Society for Clinical Investigation
American Society for Pharmacology and Experimental Therapeutics
Federation of American Societies for Experimental Biology
Society for Occupational and Environmental Health
Society for Risk Analysis
Society of Toxicology

Honors and Other Special Scientific Recognition:

Arnold J. Lehman Award, Society of Toxicology, March 1983
Editorial Board, *Regulatory Toxicology and Pharmacology*, 1981-present
Editorial Board, *Risk Analysis*, 1981-present
Head, DHHS Delegation, US/Japan Non-Energy R&D Cooperative Agreement Joint Committee Meeting, Tokyo, Japan, September 1981
Chairman, WHO Programme Advisory Committee, 1980-81
Member, WHO Programme Advisory Committee, 1980-present
Editorial Board, *American Journal of Industrial Medicine*, 1980-present
Member, Institute of Medicine, National Academy of Sciences, 1979-present
Nellie Fox Lecturer, Northwestern University Medical School, April 1978
Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78
Harrington Lecturer, University of Buffalo, April 1976
Member, NAS Safe Drinking Water Committee, 1975-1977
Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76
Associate Editor, *Journal of Toxicology and Environmental Health*, 1974-78
Editorial Board, *Archives of Environmental Health*, 1973-76
Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-present
Chairman, Subcommittee on Environmental and Occupational Health, Joint Working Group on Health Cooperation, US/Egypt Cooperative Agreement, 1972-present
US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present

US Coordinator, Biological and Genetic Consequences Project, US-USSR Environmental Protection Agreement, 1972-present
US Coordinator, US-UK Cooperative Program in Environmental Health Sciences, 1972
Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present
Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72
Associate Editor, *Cancer Research*, 1970-74
Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970
Editorial Board, *Pharmacological Reviews*, 1969-72
Chairman, National Institute of General Medical Science Pharmacology-Toxicology Review Committee, 1967-69
Member, National Institutes of Health Chemotherapy Study Section, 1965-67
Editorial Board, *Proceedings of the Society for Experimental Biology and Medicine*, 1962-65
Lecturer in Physiology, Medical School, George Washington University, 1958-62
PHS Meritorious Service Medal, 1966
DHEW Distinguished Service Medal, 1975

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| Research Interests: | Dr. Rall has authored and co-authored approximately 150 published papers relating to comparative pharmacology, cancer chemotherapy, blood-brain barrier, blood CSF barrier, pesticide toxicology, and drug research and regulation. |

## INTRODUCTION OF ASSOCIATE

Dr. RALL. Thank you, Mr. Chairman. It is a pleasure to be here.

Senator WEICKER. Oh, you're the fellow down in North Carolina.

Dr. RALL. Yes; you were going to come see us.

Senator WEICKER. Well, if they stopped talking about school prayer and other things like that—[Laughter.]—I might be able to get into the real business of the country. But in any event, I would like to come and see you, and I will.

Dr. RALL. Good.

Let me introduce on my left, Mr. Jack Rigsby, our Budget Officer.

NIEHS research seeks to understand better how environmental agents enter the human body and initiate adverse biologic reactions that may lead to disease and death. One key in this process is to identify chemicals or other agents for further research and practical environmental control.

## SUMMARY STATEMENT

I would like to briefly describe some of the research efforts carried on this last year, but first I'd like to mention what I think are three very important personnel actions. This summer, Dr. Jack Moore, who has been one of our major scientists at NIEHS, the Director of the Toxicology Research and Testing Program, was appointed the Associate Administrator for Toxic Substances and Pesticides at the EPA, one of the top jobs at EPA. Second, Dr. Bernie Goldstein, who has been our grantee for a very long time, involved in our training program, was also appointed the Associate Administrator for Research and Development at EPA. And finally, Dr. Robert Dixon, a long-time colleague of mine and head of our Laboratory of Reproductive and Developmental Toxicology, has just taken his new job at EPA as head of the Office of Health Effects.

It was always my concept that one of the main functions of NIEHS was that it would be a training ground for scientists, both in our intramural laboratories and in our grantee institutions, who would eventually staff the Environmental Protection Agency's research efforts. And I am pleased that this is beginning to happen.

This insures excellent cooperation between NIEHS and the Public Health Service and EPA. The problem now is, we have to go out and recruit to replace these very good people.

I have discussed with this committee before, the problems of the toxic chemical TCDD or dioxin, the contaminant of herbicides that has caused some problems with Agent Orange and other areas. And there is, as you all know, considerable contamination in the Times Beach area in Missouri. The Environmental Protection Agency asked us a simple question. Given the level of contamination in the dirt in the Times Beach area, is it likely that the dioxin in that dirt will be absorbed and will be toxic, if children or people ingest the dirt. So we performed a simple but very important experiment of feeding rats and guinea pigs and hamsters amounts of dioxin. Dirt samples were from the Times

Beach area and from another site, the Minker site, close by. Selection of these two sites was important, because in one the soil is sandy and in the other it is clay. We were able to show that somewhere between 50 and 70 percent of the dioxin is absorbed and, in fact, can cause serious biological damage.

If you feed a rat two to four milligrams of Times Beach dirt—and two to four milligrams will fit nicely on the head of a pin—while it will not get sick, will show definite biological changes. This, I think emphasizes the seriousness of some of the chemically contaminated areas within the country.

Let me briefly review the results of three long-term studies that we have just reported on. The first is 1, 3 butadiene, which is a component of synthetic rubber widely used in the industrial community. It had not been tested before. We tested it and it showed that butadiene is carcinogenic and this now is being looked at very carefully in the industrial environment in which it is found.

We recently reported that benzene, which is one of the most common solvents and common chemicals in the country is carcinogenic in laboratory animals, and I believe more importantly, in our intramural program and with our grantees at New York University, scientists are showing what the hemotological toxicity of benzene is, how it affects the white cells and the red cells.

And finally, we have looked very hard at vitamin C—ascorbic acid—and we are pleased to report that vitamin C, ascorbic acid is not toxic, and that is basically very good news.

Our budget request is for $183,755,000, an increase of approximately $4 million over 1984.

I'd be happy to answer any questions.

### BUDGET CONCERNS

Senator WEICKER. Where does the budget leave you, insofar as various endeavors are concerned? Are there any that cause you particular concern?

Dr. RALL. I suppose we are concerned, as most of the other institutes are, about training. We will not be able to train 66 trainees that we could at the 1984 level. We are concerned that the environmental health, toxicology, and environmental epidemiology area is growing and needs trained scientists. So the loss of those 66 trainees is serious. We feel our centers' program is terribly important. Much of the research in environmental health is complex and necessarily interdisciplinary. Our centers' budget is flat. This does not allow any increase for cost of living, and we'll have to negotiate down the request by about 5 percent. And these are the two major areas. We will negotiate now with our noncompeting grants about 2 percent and our competing about 5, and that is some cause for concern, but not as much as the other areas I mentioned.

## MARINE STUDIES

Senator WEICKER. One of the other areas that I have great interest in, both personally and in terms of my Senate duties, is the area of marine science and the oceans. I always hear of somebody throwing out the possibility of ocean dumping, when it comes to any substance that is unacceptable in terms of its disposition on land, and I get the feeling everybody sort of feels the ocean is so big, it is going to dilute whatever is out there, to the point that it is less noxious than if you put it on land.

So I have a deep concern that as the problem compounds on land, the temptation or the reality is going to take place and the ocean is going to be used as a dumping ground.

Is your Institute involved in the effects of dumping of substances into the ocean?

Dr. RALL. Not in that specific way. We have a small marine centers' program—marine and freshwater biomedical centers. I have long felt that we must observe very carefully what is happening in the marine environment, for a number of reasons. First off, the fish and shellfish will respond to toxins early and provide us an early warning system, and we see that in some areas in the Pacific Northwest. The soles—flounder—have papillomas on them, small tumors, which appear to be related to their living near the effluent of sewage treatment plants. Some fish in the Great Lakes are now beginning to show up with certain forms of tumors on their skin, which is again probably associated with some dumping.

We support a center at Duke on the east coast of the United States, a center in the Pacific Northwest and a center in Wisconsin. We hope to fund with 1984 money, thanks to the generosity of this committee, another marine center. We think these are a very good investment.

Senator WEICKER. I want to discuss that a little bit just for a few minutes here and then also personally with you, because I have a deep concern in this area. I have no doubt that the world is going to have to turn to the oceans eventually for both its food and its energy and, No. 1, I hope there's something there to turn to. And No. 2, I hope we don't do it in our usual fashion which is to, in effect, dispose of it in 10 years, whereas it should last for 10,000.

As I say, this dumping problem—people talk about nuclear waste and say, well, the ocean; they talk about toxic chemicals, well, the ocean, et cetera. And there just better be some research done, I think, to understand what we're doing, before it gets out of hand.

I'll tell you how difficult it is. I was down at the West Indies laboratory 2 weeks ago, and—this is not now related, as best I can tell right now, but to give you an idea of what can happen in the water—well, I don't know how many of you have gone swimming in the Caribbean, but you have noticed these diadena, which are the bane of every snorkeler and swimmer and skin diver, the long black porcupine-looking creatures, which some people call sea urchins. In a matter of several weeks, they have been totally wiped out—totally wiped out in the Eastern Caribbean.

It started about 1 year ago over on the Panama coast and has now just swept right through the entire Caribbean. A very pleasant occasion, I'm sure for everybody that has stepped on one. They don't have to worry about it for a while, but it's obviously quite an occurrence. And the scientists down there have been trying to get money from the Federal Government to see what happened, what has happened to these colonies and literally in weeks just wiped them out. And they have had a hard time locating that kind of money.

It's this type of thing that's going on that we really ought to be aware of. I know that isn't exactly in your area, because yours is more to man-induced situations, which apparently this is not. But I think it points up the fragility of this great resource, and if that can happen in a natural sense, you can imagine what a little bit of dumping could do. And I wonder whether we shouldn't be preparing for it in the sense of upgrading that aspect of your work.

Dr. RALL. I have been very concerned about marine studies and comparative toxicology with marine and nonmarine forms. And about 6 to 7 years ago, I perceived that many of the marine laboratories on the coasts were in prime developmental areas and were ready to really just disappear and be sold off to developers. And that is the reason, about 5 or 6 years ago, that we started the Marine Centers Program to provide core support for some of these human health-oriented parts of marine centers which are a functional entity. And we have three centers now, as I said, and I hope we will fund another one this year.

### MARINE AND FRESHWATER BIOMEDICAL CENTERS

Senator WEICKER. Where are the centers located?

Dr. RALL. Duke, on the North Carolina coast. One freshwater center at the Medical College of Wisconsin on Lake Michigan and the University of Washington in Seattle. So we are very nicely geographically dispersed. But we think there is a need for more effort. These are not expensive centers. We're talking about $150,000 each. It's really core support for them to ensure they have some money they can count on.

Senator WEICKER. And where do you propose the fourth center?

Dr. RALL. We're waiting for applications.

Senator WEICKER. And what is the amount of money that relates to your marine activities?

Dr. RALL. About $700,000 this year.

Senator WEICKER. OK. I will have staff in close touch with you. Al Stayman of my staff will be in contact with you to specifically develop your work in that area.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much. There will be other questions submitted.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: NIEHS coordinates the formulation of their budget with NIH/PHS/DHHS and there are negotiations at each phase of the budget cycle.

In the early stages of developing our 1985 budget, we were given planning levels and guidelines within which we developed and justified multiple request levels. In subsequent interactions with NIH and their interactions with the Public Health Service and the Department, these levels were reviewed and evaluated. Ultimately, decisions were made and a definite level established for our 1985 budget request. I would say that we did have input into the process and were consulted regarding the impact of some higher level decisions.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: The FY 1985 budget level provides for 347 trainees, a reduction of 66 from the 1984 level. Recent studies show that the environmental health, toxicology and environmental epidemiology areas are growing and need trained scientists. Our centers' grant budget does not increase from 1984 to 1985. Due to the complex, interdisciplinary nature of much of the research in environmental health, the centers' program is important and the flat budget of this program is cause for concern.

Nevertheless, within the 1985 budget, high priority research will be vigorously pursued. The Institute's current level of activity would be maintained over the short-term.

Question: To what extent will your new and continuation grants be funded below full cost levels?

Answer: The FY 1985 budget assumes a downward negotiation of $891,000 in competing and $754,000 in noncompeting research project grants. The rate of downward negotiation will be approximately 4.9% for competing and 2.1% for noncompeting.

Question: What important research will be delayed or eliminated as a result?

Answer: These downward negotiations are not expected to affect our funded research to an undue degree.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 1985 that you had in FY 1984 and what will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: The 1985 request for Environmental Health and Marine and Freshwater Biomedical Centers reflects an approximate 4.9% downward negotiation. This would delay funding of pilot projects and the resulting new research projects of importance in identifying health effects of environmental pollutants.

The rate at which the results of basic research is translated into prevention and treatment may be affected to some extent. However, in the short run, the 1985 funding level of our research centers should not have significant adverse impact.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: The number of research trainees will drop from 413 in FY 1984 to 347 in FY 1985. The demand for trained researchers in all our fields of support - environmental toxicology, epidemiology, pathology, and mutagenesis - is for individuals who perform basic research to better our understanding of the principles governing the interactions of chemicals with biological systems and for individuals who can estimate and/or assess the hazards to man of such exposures. Our field is young in that we have quite a way to go before we become a truly predictive science. New biomedical researchers expand our knowledge base. New methods of assessment of risk allow better and more precise regulations regarding chemical hazards. These are the primary benefits of the support of training programs for environmental health manpower. The reduction in trainees will slow our progress toward these goals.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: A recent projection of an FY 1985 budget that would support the same numbers of research grants, research and development contracts, and trainees as in the FY 1984 budget as well as in-house operations showed that it would take an additional $7,969,000 to maintain the FY 1984 level of effort.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Answer: In FY 1985 the NIEHS FTE budget level will be decreased from 719 to 688, a decrease of 31 FTEs.

The proposed reduction will be made in other-than-permanent appointments. We are currently studying the situation to determine the exact positions to be affected.

Like all other government agencies, we hope to accommodate this reduction through progress in computerization of administrative functions, OMB Circular A-76 related initiatives, and reductions in our summer student employment program. We hope to minimize the impact of this reduction on our research.

## TOXIC WASTES

Question: Last year you gave us a concise but useful picture of the problem with toxic waste dumping in the United States. You made it clear that one of the big mistakes has been putting toxic chemical pits in porous ground over important aquifers.

You made the point that we have identified about 10 percent of the chemicals contaminating these aquifers, but we don't know what the 90 percent are. Any progress on the problem of identifying the 90 percent?

Answer: Yes, rather substantial progress has been made in identifying chemicals contaminating aquifers from which groundwater supplies are derived. According to the information available to the Hazardous Waste Information Evaluation Subcommittee (HWIES) of the DHHS Committee to Coordinate Environmental and Related Programs (CCERP), about 420 different substances or classes of substances have been identified at 881 superfund sites currently on the data base. The number of substances or classes of substances observed in groundwater amounts to some 170 chemicals.

Many chemicals found at superfund sites, and thus contaminating aquifers, are being tested by NTP; in fact, 65 of these chemicals have been included in the chronic toxicity testing program and 70 compounds in the environmental mutagenesis and short-term testing program. In addition to classical toxicological studies, an attempt will be made to look at the presence or absence of interactions which may arise from exposure to a mixture of chemicals such as simulated dump site mixtures.

A model is now being developed at the NIEHS that will make it possible to predict concentrations of chemicals in groundwater resulting from disposal practices for industrial, agricultural, and municipal wastes. This model combines the soil processes with climatic conditions that jointly control the movement of chemicals through soil towards the water table and influence chemical transformations that may occur during this passage.

Question: You pointed out that among the 10 percent we know about are solvents which can, among other things, cause kidney disease. You said you had a study going to see whether there was a connection between end stage renal disease and exposure to such solvents. Any results yet?

Answer: The Environmental Factors and Chronic Renal Failure Study is currently being conducted. Patients with renal disease have been selected for the study and interviews are planned. The study will obtain information on exposure to solvents along with information on other occupational and environmental exposures. Preliminary results are not expected to be available until 1985.

Question: You also said you feel "Scientifically very uncomfortable" with "combination toxicity" which happens when one is exposed to a number of compounds at once. You were going to have some scientific meetings devoted to this problem. Did you learn anything at these meetings - and what, if anything, is your research on "combination toxicity" showing?

Answer: NIEHS supported a scientific meeting on methods for testing and evaluation of complex mixtures through the International Programme on Chemical Safety in August 1983. Two major methodological problems were considered: (1) how to interpret the results of tests using complex mixtures as they occur, for example, in toxic waste dumps or in contaminated water; and (2) how to combine the results of tests with single chemicals in order to assess the effects of these chemicals acting together. The main conclusions of this meeting were as follows:

- Additional research should be conducted to advance the methodology of bioassays for mixtures of chemicals, including further development of short-term tests, whole animal long-term tests, and various combinations of such tests.

- Critical to the interpretation of studies on human health effects of chemicals is further research on interactions that may result from exposure to mixtures of chemicals. The joint action of chemicals may be additive, more than additive (synergistic), or less than additive (antagonistic).

- Records, record-linkage systems and data bases to facilitate epidemiological surveillance of populations exposed to chemical mixtures, should be strengthened. Epidemiological studies should also be coordinated more closely with, and reinforced by, complementary clinical and laboratory investigations.

- Further research on biological mechanisms of interactions, particularly those that are likely to produce synergism, is indispensable for better understanding of the joint action of chemicals.

- There is a need for reliable methods for detecting the ability of mixtures of chemicals to promote tumor incidence in experimental animals. These methods, in combination with short-term tests for detecting initiators of carcinogenesis, could eventually help to find alternatives to expensive and time-consuming animal testing for carcinogenicity.

NIEHS is currently negotiating a contract with the National Academy of Sciences to support a study of the scientific basis for assessing chemicals in mixtures. A report should be published within two years which sets forth the current state of the problem, strategies for undertaking biological tests of mixtures of chemicals, and recommendations and priorities for needed research.

An international group of experts in toxicology and carcinogenesis research and testing was convened in Lyon, France to develop guidelines to assist in the priority selection of chemicals and complex mixtures needing toxicologic characterization. The meeting was organized by the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO). The NIEHS was a participatory member of the _ad hoc_ working group. An IARC report is in preparation and should be issued soon.

### EDB

Question: We have heard much recently about a toxic substance called "EDB" -- ethylene dibromide. There was concern about contamination of certain foods -- and recently we have heard it is used in leaded gasoline. What can you tell us about this substance, its toxicity and any role you played in identifying the danger to health?

Answer: Ethylene dibromide (EDB), a colorless volatile liquid, is used widely as a lead scavenger in leaded gasolines and was used until recently as a soil and grain fumigant, mainly as a nematocide. The use of EDB as a fuel additive appears to be decreasing as leaded gasoline for automobiles is apparently being phased downward. More than 100 formulated pesticides contained EDB. Lower volume uses are as a dye intermediate, an industrial solvent (for resins, gums, waxes), and as an ingredient in some fire extinguishers. In 1977, over 260 million pounds were produced in the United States.

NIEHS scientists and scientists from other DHHS organizational units prepared a background document on EDB. Items covered included data on EDB use and exposure levels; results of laboratory carcinogenicity, mutagenicity, teratogenicity, and reproductive studies; results of epidemiologic investigations; information on metabolism and tissue distribution; and a brief discussion of some of the issues involved in risk assessments for EDB.

EDB affects liver microsomes, DNA, and sperm. Human exposure to EDB can cause eye, skin, and respiratory irritation as well as damage to the liver, kidney, spleen, and lungs.

The results of the carcinogenicity studies conducted by the NCI/NTP were published in technical reports. These reports were made available to the EPA by the Public Health Service. In addition, a summary publication by the NTP on this chemical (_Environmental Health Perspectives_, 1983) was widely disseminated to government agencies and to interested individuals.

Question: Are there substitutes for EDB and are they being put to use?

Answer: The following are brief descriptions regarding the toxicology of commonly mentioned substitutes for EDB:

## Carbon Tetrachloride

Carbon tetrachloride is carcinogenic to mice and rats. Liver neoplasms were produced following its administration by various routes. Mammary neoplasms were induced in rats following subcutaneous injection of carbon tetrachloride. Evidence for carcinogenicity to humans is considered inadequate. Chronic exposure to carbon tetrachloride causes liver and kidney injury in experimental animals.

## Carbon Disulfide

No information is available on the carcinogenicity of carbon disulfide. An earlier NCI bioassay on carbon disulfide was considered inadequate because of poor survival rates in both the rats and the mice. In one experiment considered short in duration, repeated exposure of carbon disulfide for up to one year did not produce tumors in experimental animals. NTP is conducting a prechronic six-month inhalation toxicity study; the work is in progress. A chronic two-year study to determine carcinogenic potential in laboratory animals is under consideration. A recent report of an industrial-sponsored 90-day inhalation study of carbon disulfide in rats and mice indicated that the most significant findings are axonal swelling of nerve fibers and segmental degeneration in peripheral nerves. This may indicate a potential hazard of neuropathy could exist for humans who may be repeatedly exposed to carbon disulfide.

## Methyl Bromide

A recent paper (Toxicology and Applied Pharmacology. 72: 262-271, 1984) by scientists at the National Institute of Public Health, The Netherlands, reported that methyl bromide administered by oral gavage as a solution in arachis oil was carcinogenic in the forestomach of rats in a 90-day experiment. In late FY 1984 NTP is scheduled to start a two-year inhalation exposure toxicity/carcinogenicity study in mice. Since methyl bromide is a gas at ordinary temperatures and has essentially no warning properties, dangerous concentrations may rapidly accumulate in a work area without warning to workers (Torkelson and Rowe, Patty's Industrial Hygiene and Toxicology, 3rd Ed 1981). Inhalation exposure to higher concentrations causes lung irritation and congestion and edema. As reported in the literature, food fumigated with methyl bromide (3 lb/100 cu ft) was fed to rats and rabbits for 20 and 52 weeks, respectively. Other than a slightly lower weight gain in the exposed rabbits, no appreciable toxicologic effects were observed.

Telone II

NTP will report the findings of carcinogenicity studies in rats and mice given Telone II by gavage in July 1984. In other reported experiments, weekly subcutaneous injections of cis-1,3-dichloropropene (the major ingredient in Telone II) to mice for 538 days produced fibrosarcomas at the injection site. Repeated dermal applications did not produce any significant incidences of tumors. A six-month inhalation toxicity study was conducted on 1,3-dichloropropene in rats, rabbits, guinea pigs, and dogs. Following low level exposure (3 or 1 ppm) for six months the only effect attributable to exposure was a cloudy swelling of the renal tubular epithelium in male rats at the high dose. However, at higher concentrations (50 or 11 ppm) for 1 month, 1,3-dichloropropene vapor caused kidney and liver injury.

Ethylene dichloride (EDC; 1,2-dichloroethane)

Ethylene dichloride may be used as a substitute for EDB; 460 metric tons of EDC were reportedly used as a grain fumigant in 1979. The carcinogenic potential of EDC given by gavage was shown by NCI carcinogenesis studies in rats and mice. In another chronic bioassay in rats and mice by inhalation no increase in tumor incidence was reported. The difference between these two bioassays may be due to different exposure concentrations as well as to pharmacokinetic factors often dependent upon the route of exposure. EDC has not been reported to cause any remarkable toxicity in animals after repeated exposure. Acutely, however, EDC produces damage to liver, kidneys, adrenals, and lungs.

As further information, the Environmental Protection Agency (EPA) recently (February 1984) prepared a background document on EDB that discussed possible substitutes. Following is the one substitute from the EPA document not included above:

Aluminum Phosphide

Aluminum phosphide is formulated as tablets or pellets which liberate highly toxic phosphine gas when the aluminum phosphide reacts with moisture in the commodity or surrounding air. Because of the highly toxic nature of the phosphine which is liberated, formulations of aluminum phosphide have also been considered as highly toxic materials (EPA, 1981).

A two-year rat feeding study examined the effects of feeding diets fumigated with phosphine gas to rats (Hackenberg, 1972). Analytically determined levels of phosphine in the diet ranged from 0.2 ppm to 7.5 ppm and averaged approximately 1 ppm. No differences were found between control animals and those animals receiving treated diet with respect to growth, food consumption, survival, morbidity, hematology, blood chemistry, and gross and microscopic pathology.

Question: To what extent were you aware of the problem with EDB before the recent furor broke over us, and what warnings, if any, did you give the Environmental Protection Agency and the public?

Answer: The laboratory animal toxicology associated with EDB exposure has been well documented and long recognized. Mutagenicity has been known since 1969. The carcinogenicity in rodents by oral exposure was established and reported first in 1973 by the NCI as a brief communication; other publications followed, and a technical report was issued in 1978. Exposure of laboratory animals by inhalation was shown to be carcinogenic as reported publicly by the NTP in June 1980; the full technical report was published in 1982. These results and subsequent reports were known at the time to the EPA, other governmental organizations, the scientific community, and the public.

Question: What can you tell us about the problem of leaking underground storage tanks? I gather this problem goes beyond leaks from gas station tanks?

Answer: A large number of the existing underground gasoline storage tanks in the United States were installed around World War II. As these metal tanks reach the end of their functional life and begin corroding, they leak. From a public health perspective such leakage is of great concern if it results in contamination of potable ground water supplies.

To define more precisely the nature and magnitude of the potential health threat, information is needed on the concentration and rate of movement of major gasoline constituents - benzene, EDB, toluene, lead, isooctane - in aquifers adjacent to storage tanks, and the toxicity of these chemicals in mixture with other ground water contaminants.

In addition to retail gas stations, other potential sources of underground gasoline leakage include public and private storage facilities and underground pipelines for petroleum transport. However, concern is not limited to gasoline alone. Other liquid fuels, chemicals and radioactive wastes stored underground in storage tanks and disposal sites migrate into groundwater. This problem of contaminated groundwater resources and the implications for human health are of concern to other federal departments and agencies including Defense, Energy, and EPA.

## HEALTH SCREENING STUDY

Question: We understand you are conducting some sort of health screening study involving hundreds of residents of North Carolina. What are the specifics and how much is this costing?

Answer: The Breast Milk and Formula study is being done in North Carolina. In this study, we are following 850 children from the time of their birth to age five. The study began in 1978; the oldest child is now six, while few are younger than two. We measured the levels of Polychlorinated Biphenyls (PCBs) and DDE (a form of DDT) in breast milk and found that almost all samples had small but measurable amounts of both chemicals. We monitor breast fed children for the length of breast feeding, occurrence of illness, growth, and development. The study cost about $240,000 last year; costs are now declining, since the children have begun to "graduate."

Question: What benefits will we get from this study in North Carolina?

Answer: Pollution of breast milk is a worldwide phenomenon, and there have been no large-scale studies in which both the child's clinical course and the pollutant chemicals have both been examined. Because of this lack of data, it is very hard to know whether a given mother should have her milk tested, and, if she does, what levels of pollutants might be safe or dangerous. This study should be a step in the direction toward knowing if these chemicals actually pose a hazard to the newborn, and, if so, at what levels they do so.

Question: Have similar studies of residents of other states been considered or undertaken?

Answer: There have been many studies of the presence of environmental chemicals in breast milk, both in the USA and abroad. All are fairly consistent and show that PCBs, DDT, and several other pesticides can be readily detected in a high proportion of breast milk samples. We are only aware of two other studies, both small and as yet unpublished, in which chemicals were measured and the children were followed; one is in Michigan, and the other in Hawaii.

## SUBCONTRACTOR CLAIMS

Question: A year or two ago you were faced with claims filed by subcontractors on the new Environmental Health Sciences building in North Carolina. The claims apparently related to delays in scheduling construction and to alleged design defects. At the time it appeared there could be claims totaling between $13 million and $20 million. Where does the matter presently stand and what will be the extent of the government's liability, if any?

Answer: To date, claims against the government total $21 million. Claims totaling $10 million have already been settled at a cost of about $5 million. To date, the U.S. Treasury has paid approximately $3.5 million of these settlements. Claims totaling about $11 million are presently outstanding.

In a recent major court decision the U.S. Court of Appeals ruled that the subcontractors cannot sue the government directly, but that they may sue the government only through the primary contractor. This represents a reversal of a previous decision by the Armed Services Board of Contract Appeals. In September, 1984, the Armed Services Board of Contract Appeals is scheduled to establish whether the Department or the primary contractors is liable for subcontractors claims.

Several of these are scheduled to be heard in September 1984 by the Armed Services Board of Contract Appeals. The government's liability will eventually be determined by this Board.

Question: Have you identified the cause of the problem? We understand it may have stemmed from inexperience in dealing with such a large building project.

Answer: First, we understand that construction claims are not unusual for a project of this size, but in this case we believe that we can identify multiple causes. The complexity of the construction must have been one factor. Also, we understand that some of the problem arose from ambiguity in the contractual language between the government and the construction manager as well as from the relationships between the contract manager and subcontractors. Nevertheless, I am very pleased to tell you that the building is now occupied by scientists and fulfills the needs for which it was constructed. We are actually very pleased with the outcome.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### OSHA

Question: Dr. Rall, in your prepared testimony you refer to an applied dioxin study that the National Toxicology Program conducted at the request of the Environmental Protection Agency.

Can you tell us if you have done any work for the Occupational Safety and Health Administration (OSHA) in the last two years?

Answer: The NTP is currently testing in long-term carcinogenicity bioassays a number of chemicals nominated to the Program by OSHA. The NTP is also conducting a testing initiative on dyes derived from the carcinogen benzidine and its structural analogs. This initiative was undertaken at the joint request of OSHA, the Environmental Protection Agency, and the Consumer Product Safety Commission, following in-depth review and discussions by representatives of the nominating agencies and NTP staff. Within the last year OSHA nominated the chemical 2,6-xylidine for inhalational carcinogenicity testing by the NTP. This chemical is currently being evaluated for testing, and a decision as to whether to test it is expected later this year from the NTP Executive Committee.

Question: Describe in as much detail as possible your interactions with OSHA over the last 12 months.

Answer: OSHA has participated in all of the organized activities of the NTP within the last year. Representatives from OSHA attended the three meetings of the NTP Executive Committee held in FY 1983, as well as the one meeting held thus far in FY 1984. This Committee is the primary advisory group to the Program. OSHA staff participated in the review and approval of the NTP FY 1983 and FY 1984 Annual Plans and voted on the chemical selections for in-depth toxicological evaluation by the NTP.

Two representatives from OSHA are members of the NTP Chemical Evaluation Committee (CEC) which consists of one or two scientists from each of the agencies participating in the NTP. OSHA staff attended the three meetings of the CEC held within the last year, and participated in the review of nominated chemicals and the development of Committee testing recommendations.

A representative from OSHA is a member of the Working Group for the Annual Report on Carcinogens. This document is prepared annually by the NTP and contains substances and processes known or reasonably anticipated to be carcinogens to which persons in the U.S. are exposed. Last summer the Working Group selected the new chemicals for the Fourth Annual Report on Carcinogens. The OSHA representative suggested a number of chemicals that were accepted for inclusion in the fourth report. OSHA staff subsequently updated their submissions on previously selected chemicals for entry into the fourth Annual Report.

The NTP notifies staff from participating agencies of preliminary results regarding chemicals that appear to pose hazards. A recent example involves 1,3-butadiene, an important chemical in the synthetic rubber industry which was tested by the NTP in an inhalational carcinogenesis study in mice. Preliminary, unverified results indicated the chemical to pose a potential carcinogenic hazard. OSHA was quickly alerted that a possible toxicity problem existed. When the pathology results were finalized, the data were supplied to relevant OSHA staff. A meeting was held on August 22, 1983, of NTP scientists responsible for the study and staff from all the NTP agencies, to discuss the results and to assess further testing needs.

On September 15, 1983, OSHA held a meeting on 1,3-butadiene which was attended by representatives from the rubber manufacturers, the labor unions, academia, NTP, and other health research and regulatory agencies. Issues pertaining to the health effects data and to workplace exposure were discussed.

In January 1984, the NTP initiated a testing initiative on 1,3-butadiene to investigate the mechanism of the chemical's carcinogenicity and the differences in species senstivity to the chemical. At the January 27, 1984 meeting of the NTP Executive Committee, an NTP staff member reported on this initiative. At this meeting, representatives from OSHA and EPA also discussed activities on 1,3-butadiene underway at their agencies.

In March 1984, NTP staff members met with a representative from OSHA and an industry scientist to discuss in more detail NTP's planned testing and studies that industry may consider performing. As the NTP work on 1,3-butadiene progresses, NTP staff will inform representatives from OSHA and the other participating agencies of the results.

In similar fashion, the NTP informed OSHA and the other agencies of the preliminary positive results from the NTP carcinogenesis study of benzene in rats and mice. Benzene is a known human carcinogen for which supporting data in animals had been lacking until recently. First the final pathology tables were submitted to OSHA; when the draft report on the study was later completed, it too was forwarded to OSHA.

At the January 27, 1984 meeting of the NTP Executive Committee representatives from the National Institute of Environmental Health Sciences, OSHA and EPA gave presentations on activities underway at their representatative agencies, and a representative from academia reported on the conclusions of an international conference on benzene.

Interactions of this nature will continue in the future on potentially toxic chemicals tested by the NTP and of concern to the health regulatory agencies.

Question: Are there any institutional mechanisms in place that allow you to routinely consult with the experts at OSHA on a periodic basis?

Answer: Yes, as noted above, OSHA participates in the NTP Executive Committee, which consists of the heads of the four health regulatory agencies and of four of the health research agencies. Two scientists from OSHA are members of the NTP Chemical Evaluation Committee, which meets three times annually to evaluate nominations for toxicological testing. Also, one representative from OSHA is a member of the NTP Working Group for the Annual Reports on Carcinogens, which each year selects new chemicals for inclusion in the upcoming report.

NTP staff notify OSHA representatives of preliminary results regarding chemicals that appear to pose hazards on the basis of NTP studies. Draft technical reports of all NTP carcinogenesis studies are forwarded to OSHA staff prior to being reviewed by the NTP Technical Reports Peer Review Panel. OSHA staff are informed in advance of all meetings of this Panel and encouraged to attend.

Finally, when NTP chemical managers develop testing protocols for chemicals of concern in the workplace, they contact OSHA scientists for their input on the design of these studies.

## NATIONAL INSTITUTE ON AGING

**STATEMENT OF DR. T. FRANKLIN WILLIAMS, DIRECTOR**

**ACCOMPANIED BY:**

- **DAVID CHICCIRICHI, EXECUTIVE OFFICER**
- **DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. All right. Now we have the National Institute on Aging. The budget request is $117 million or about $2.5 million more than 1984. Dr. T. Franklin Williams, the Director, is here to testify.

Welcome, and introduce your associates and proceed with your statement.

[The statement follows:]

## STATEMENT OF DR. T. FRANKLIN WILLIAMS

It is a pleasure to appear before you this first time to present the Fiscal Year 1985 budget for the National Institute on Aging and to report on recent progress in aging research. I'd like to spend most of my time talking about the areas of research which account for the greatest commitments of NIA efforts and resources: Alzheimer disease, the lengthening life expectancy, maintaining health, and training for academic leadership in geriatrics and gerontology.

A field of continuing high priority is that of research on dementia in older people. Although systematic studies of age-related changes in the human brain have a 100-year history, until recently few investigators were interested in this subject. During the last few years, a growing number of neuroscientists have begun to study a broad range of topics in the neurobiology of aging and dementing disorders of the aged. Only a decade ago, very little was known about "senility." The medical condition known as senile dementia was considered a hopeless affliction of the aged. Alzheimer disease was a relatively unknown entity among the medical and scientific communities, and far from the household word it has become today. The pace of scientific progress in this area of research has been truly remarkable. Now is a crucial time to capitalize on the scientific momentum in the neuroscience of aging if we are to make progress in preventing and treating the dementing disorders of the aged.

Among the significant advances of the past year has been the documentation by the NIA's Laboratory of Neuroscience of the marked decrease in brain cell metabolism which occurs in Alzheimer disease. This has been measured in affected patients using the non-invasive technology of positron emission tomography screening, as well as measuring differential glucose metabolism in various portions of the brain. As a part of this work our investigators have also shown that there is no decline in brain glucose metabolism with normal aging. This work lays the foundation for further studies of metabolic changes in Alzheimer disease.

During the past few years, findings have linked an infectious agent known as a prion to Alzheimer disease and to several other degenerative brain disorders. More recent evidence suggests that prions and amyloid plaques (areas of debris left by degenerating nerve cells) may have structural and chemical properties that are indistinguishable. If further studies prove that prions and amyloid are the same, we may see a major breakthrough in understanding the etiology of not only Alzheimer disease, but other degenerative brain diseases as well. Another important discovery is the finding that fetal brain tissue transplants can survive and function normally in older animals. When such procedures are perfected through further animal studies, they may prove to be useful therapeutic tools. This form of treatment may enable us to restore lost neurochemical function in various parts of the brain. Genetic studies related to Alzheimer disease are providing very exciting and unique opportunities, particularly in light of the recent "bracketing" of a potential Huntington's disease gene. Also, such procedures as recombinant DNA research and products such as monoclonal antibody were developed for the study of cell biology and membrane phenomena but are proving to be very useful for the study of pathological processes in aging and Alzheimer disease.

In addition to studies of what causes Alzheimer disease and how to treat it, the NIA has considerable interest in research on the diagnosis of the disorder. As yet, medical science has no tools to diagnose Alzheimer disease accurately in living patients. While many advances have been made, most of what we know about the disease comes from studies of severely ill individuals. Understanding the basic mechanisms of the disease and developing a means to cure or prevent it requires that we find a way to diagnose the disease accurately when it first strikes. For example, tests of possible drug therapies will yield ambiguous results unless scientists know that the patients they are studying suffer from the same type of demetia.

In December 1983, the American Association of Retired Persons, the National Institute on Aging, the National Institute of Neurological and Communicative Disorders and Stroke and the National Institute of Mental Health sponsored a Research Workshop on the Diagnosis of Alzheimer Disease. The meeting brought together practicing physicians and research scientists who have taken leading roles relevant to Alzheimer disease in six diverse fields: neuropsychology, psychiatry, neurology, neuropathology, neurochemistry and neuroradiology. At the close of the meeting, the participants concluded that each specialty has relatively standard criteria to diagnose Alzheimer disease in its late stages, but there are no specific tests that can be recommended to the general practitioner who sees minor problems and suspects Alzheimer disease. Each of the six panels did, however, make a number of valuable suggestions that will help the NIA and other Federal research Institutes plan for future studies related to the diagnosis and course of Alzheimer disease.

Last year, Congress provided funds to support up to five specialized centers to conduct research on Alzheimer disease and related dementias. The centers will bring together clinical and basic science investigators to enhance the effectiveness of Alzheimer disease research and ultimately health care delivery. The new research studies proposed by applicants will need to be based upon a preexistent program of research on Alzheimer disease and related dementing disorders of the aged. When fully developed, the centers will also train postdoctoral fellows and health professionals to conduct research on Alzheimer disease and its management; train health care professionals in the management of Alzheimer disease through continuing education and information programs; develop a model demonstration facility for training, education, and treatment; and quickly transfer advances in the field of Alzheimer disease research into improved care for the Alzheimer patient.

With increasing longevity and growth in absolute numbers of older people, the need for improved health and functioning will become overwhelming before the end of the century. There is a pressing need to discover the mechanisms by which age-related declines may be prevented, reversed or ameliorated. Recent research findings are suggesting ways to extend the productive middle years; to prevent or postpone the many disabilities of old age; and to contain the costs of health care and dependency.

Intellectual functioning, memory, perception, and psychomotor skills in older individuals have been found to be widely variable and quite malleable. Contrary to conventional wisdom, few healthy individuals at age 60, and fewer than half even at age 80, show significant decrements in cognitive test performance. Given training and incentives, elderly people can learn to perform as well on tests as people 20 years younger. Deficits in reaction time that sometimes affect performance can often be remedied. New studies are looking for ways to measure components of intellectual functioning that draw upon experience and may develop or improve in middle or later life. Further intensive study is needed of specific cognitive, perceptual, and neuropsychological processes that can affect older people's productivity and effective functioning in everyday living.

Aspects of lifestyle, in particular nutrition and exercise, are commanding a great deal of research attention. At the NIA, research on nutrition is attempting to define the nutritional requirements for good health in the elderly; to determine how dietary deficiencies are associated with depressed immuno-competence, depressed cognitive function, or overt metabolic disease; and to determine how eating behaviors change with aging. Research on exercise physiology examines how physiologic (e.g., pulmonary, cardiovascular, or neuromuscular) adaptation to exercise is altered by aging, and whether regular long-term physical activity can help prevent such age-related disorders as hypertension, maturity onset diabetes mellitus, and osteoporosis.

The primary aim of geriatrics is to maintain effective functioning and independence in living for older people, to the maximum extent possible, in the face of chronic diseases and disabilities. The extent to which we can improve our capabilities to address such problems successfully will largely determine what the burden of care is going to be for individuals, families and society, as the number of old and very old people rapidly increases. A number of disorders and diseases that afflict older people and result in disability and institutionalization have received too little attention from the medical research community. These include such major functional disabilities as urinary incontinence and problems of mobility with the frequently associated complications of falls and hip fractures. The NIA is developing programs to address these conditions specifically.

Over the past three years, the NIA has conducted several developmental activities in the area of urinary incontinence, including very promising intramural research on the use of biofeedback. Preliminary results from both intramural and other research suggest that behavioral therapies and biofeedback may be effective in preventing urinary incontinence in older persons. This research on biofeedback will soon be extended to institutionalized elderly patients with urinary incontinence. In addition, an initiative is being organized to study detrusor dysfunction, a major cause of urinary incontinence.

There is greatly increased disability and death among those who fall, including the devastating and expensive problem of hip fracture. Falls in older persons are associated with a number of risk factors, including gait and balance disorders, neuromuscular dysfunction, impaired vision and hearing, impaired mental function, and the side effects of drugs. Environmental hazards also frequently contribute, but are rarely the sole cause. Some research on falls is already under way through support from the Teaching Nursing Home grants. To stimulate more interest in this area, the NIA is planning a research workshop to understand better the factors contributing to falls.

Our perceptions of the manifestations of aging are changing with the lengthening life expectancy and with changing patterns of morbidity and loss of function. Information on these changes is still limited. Demographic and epidemiologic studies are in progress which are emphasizing the needs of the vulnerable, rapidly growing population over age 85 and are exploring trends in mortality, morbidity, disability and everyday functioning. One NIA study is following a total of 10,000 people over age 65 to determine patterns over time of health and diseases, functional status, risk factors, behavioral, social and environmental interplay, and health outcomes, as well as histories of health services utilization and institutionalization. A follow-up of the National Health and Nutritional Examination Survey I is providing extensive data on the relationship of specific diseases with detailed prior information on physical and mental health, occupation, health-related behavior, and numerous other variables. Other studies are being pursued to obtain a better understanding of "normal" biological and psychological aging and of changes that occur with age but are due to diseases or to other external environmental factors. We are currently developing rodent colonies for use in the development of biological markers of aging. Of particular interest is the fact that these colonies will include dietary-restricted animals, which may be the ideal subjects for aging studies because they attain the species maximum lifespan. We are also in the final steps of developing biomarkers of aging primates. Such markers will also be useful for evaluating segmental interventions in aging processes.

In 1985 the NIA will undertake a major new emphasis in the area of molecular biology. The last few years have seen the emergence of powerful new techniques such as molecular cloning and gene transfer which have provided valuable information on the mechanism of cancer at the molecular level. It is now appropriate to apply this technology to examine the nature of aging at the molecular level. This may permit the development of effective strategies for promoting maintenance of health and the prevention of age-related disease.

A major challenge which continues to face us is geriatric training. Two major interrelated approaches to education are: 1) training investigators to pursue the enlarging research opportunities, and 2) preparing faculties to teach these topics to present and future health professionals. During the latter part of 1983, I had the privilege of chairing an interagency task force on training in geriatrics and gerontology, appointed by the Assistant Secretary for Health in response to a congressional request for a plan to enhance training in these fields. This task force considered a broad range of training issues related to the preparation of personnel in these fields. Particular attention was given to the training of faculty for geriatric and gerontological education; practitioners in the various fields of health and social services involved in delivering care to older Americans; and investigators needed to carry out research on biomedical, clinical, behavioral, health services, social, and related issues. Specific considerations included the estimated needs for faculty, researchers, and practitioners through 1990 and 2000, information on the extent to which current approaches and activities are likely to meet the identified needs, and recommendations for further training approaches and activities that might help meet the identified needs.

This summarizes those areas that are of high priority for the National Institute on Aging. Mr. Chairman, the FY 1985 budget request for the National Institute on Aging is $117,390,000, an increase of $2,472,000 over the comparable FY 1984 level. I will be pleased to answer any questions you may have.

## BIOGRAPHY OF DR. T. FRANKLIN WILLIAMS

Birthdate: November 26, 1921 - Belmont, North Carolina

Education: B.S., University of North Carolina, 1942
M.A., Columbia University, 1943
M.D., (Cum Laude) Harvard Medical School, 1950

Professional History:

| | |
|---|---|
| 1983 to present | Director, National Institute on Aging, NIH |
| 1983 | J. Lowell Orbison Alumni Distinguished Service Professor |
| 1982 to 1983 | Director of the Geriatric Unit, Monroe Community Hospital, Rochester, N.Y. |
| 1980 to 1983 | Co-Director, Center on Aging, University of Rochester Medical Center |
| 1968 to present | Professor of Medicine and of Preventive, Family and Rehabilitation Medicine, University of Rochester |
| 1968 to 1982 | Professor of Radiation Biology and Biophysics, University of Rochester |
| 1968 to 1982 | Medical Director, Monroe Community Hospital, Rochester, N.Y. |
| 1977 | L.S. McLeod Visiting Professor of Geriatric Medicine, University of Adelaide and South Australia Postgraduate Medical Education Association |
| 1956 to 1968 | Instructor to Professor of Medicine and of Preventive Medicine, University of North Carolina |
| 1954 to 1956 | Fellow in Medicine, University of North Carolina |
| 1953 to 1954 | Assistant in Medicine, Boston University |
| 1953 to 1954 | Senior Resident Physician, Boston Veterans Administration Hospital |
| 1950 to 1953 | Intern and Assistant Resident Physician, John Hopkins Hospital |
| 1942 to 1943 | Assistant in Chemistry, Columbia University |

Military Service:

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|---|---|
| 1983 to present | Assistant Surgeon General, U.S. Public Health Service |
| 1943 to 1946 | Communications Officer, U.S. Naval Reserve, active duty |

Societies and Associations:
American Association for the Advancement of Science (Fellow)
American College of Physicians (Fellow)
American Federation for Clinical Research
American Public Health Association (Fellow)
American Society of Human Genetics
American Geriatrics Society
American Diabetes Association
Society for Experimental Biology and Medicine Rochester Academy of Medicine
New York and Monroe County Medical Societies
Gerontological Society of America
New York State Public Health Association
Institute of Medicine, National Academy of Sciences
The Royal Society of Medicine
Academia Medicorum Litteratorum

### Other Appointments:

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|---|---|
| 1965 to 1968 | Member, Southern Regional Council |
| 1968 to 1973 | Member of Board of Monroe County Arthritis Chapter |
| 1968 to 1982 | Advisory Board Member, University of Rochester School of Medicine and Dentistry |
| 1969 to 1971 | Consultant, Citizens Board of Inquiry on Health Services to Americans |
| 1970 to 1972 | Chairman, Chronic Care Subcommittee, Genesee Regional Health Planning Council |
| 1970 to 1974 | Member of Health Services Research Study Section |
| 1971 to 1973 | Chairman, Chronic Illness and Aging Committee, Medical Society of Monroe County, New York |
| 1971 to 1976 | Member of Board of Kidney Foundation of Genesee Valley, Rochester, New York |
| 1972 to present | Member of Medical Advisory Board, St. Ann's Home |
| 1973 to 1976 | Chairman, Rehabilitation Task Force, Health Council of Monroe County |
| 1974 to 1976 | Member of Board of Westside Health Center |
| 1974 to 1977 | Member of Board of the Hearing and Speech Center of Rochester |
| 1975 | Chairman, Committee on Long Term Care, Genesee Region PSRO |
| 1975 | Consultant and Chairman, Work-Group on Treatment, National Commission on Diabetes |
| 1975 | Consultant on Institutional Long Term Care Studies, Health Services Criteria Project, University of Washington |
| 1975 to 1978 | Member of Health Services Developments Study Section |
| 1975 to 1981 | Member of Board of Rochester Area Multiple Sclerosis Society |
| 1976 to 1979 | Member, Regional Chronic Care Council, Finger Lakes Health Systems Agency |
| 1976 to 1983 | Member of Board, Executive Committee and of Professional Advisory Committee, Monroe County Long Term Care Program, Inc. |
| 1978 to 1981 | Advisory Board to National Information Clearinghouse on Diabetes |
| 1978 to present | Member of Board of Episcopal Church Home, Rochester, New York |
| 1979 to 1981 | Consultant to American Board of Internal Medicine (on geriatric questions) |
| 1979 to 1981 | Member Long Term Care Policy Task Force of New York State Health Planning Commission |
| 1979 to 1982 | Chairman, Dean's Committee of Veterans Administration Hospital, University of Rochester |
| 1979 to 1983 | Coordinator, Aging Cluster, University of Rochester |
| 1980 to 1983 | Member, Health Services Research Review Board, Veterans Administration |
| 1980 to 1983 | Member, Rochester Area Hospitals' Corporation and its Medical Advisory Committee |
| 1980 to 1983 | Consultant, Geriatric Medicine, Veterans Administration Medical Center, Buffalo, N.Y. |
| 1981 to 1983 | Member, Editorial Advisory Board for Medicine in Old Age Series |
| 1981 to 1983 | Member, Advisory Council, Monroe County Office for the Aging |
| 1981- | Member, Board of Directors, American Federation for Aging Research |
| 1981- | Editorial Consultant, Journal of Chronic Diseases |
| 1982 to 1986 | Member, VA Geriatrics & Gerontology Advisory Committee |
| 1982 | Consultant, Geriatric Medicine, VA Medical Center, Canandaigua, N.Y. |

### Honors and Awards:

Phi Beta Kappa
Alpha Omega Alpha
Sigma Xi
Member, Institute of Medicine
Diplomate, American Board of Internal Medicine
Diplomate, National Board of Medical Examiners
Markle Scholar in the Medical Sciences
Special Fellow, Department of Physiology, Vanderbilt University
Honorary Member, American Academy of Orthopedic Surgeons

### Publications:

Author of over 112 scientific papers and abstracts.

## INTRODUCTION OF ASSOCIATES

Dr. WILLIAMS. Senator Weicker, I'd like to introduce first, Mr. David Chicchirichi, our Executive Officer. I would also like to say that I'm honored to follow Dr. Butler and Dr. Ringler in representing the National Institute on Aging.

## CONTRIBUTIONS TO THE FIELD OF AGING

My own experience in care of older people and in teaching and research in geriatrics has certainly convinced me of the importance of the mission of the National Institute on Aging in promoting and supporting research and training in the biomedical, behavioral, and social aspects of aging and the problems of older people. I am very much aware of the contributions already made by this Institute. I would like to cite a few of the Institute's recent accomplishments. One is the striking increase in the numbers of research contributions to the aging literature that has occurred since the National Institute on Aging was begun 7 years ago. The number has doubled from about 1,000 research publications a year to 2,000 per year, a doubling rate about every 7 years.

Second, the Baltimore longitudinal study of the aging, which began 25 years ago under other auspices in NIH, celebrated its 25th anniversary this year. A publication summarizing many of the research findings from this study is at the printer's now.

In the past year, some of the important research done through this study has shown that cardiac function is maintained at a normal level, even under maximum stimulations in older people who are free of coronary artery disease. This points up the importance of making the distinction between aging and disease—disease conditions that can be prevented or treated.

Another similar example in recent research from some of our extramural support shows that normal mental functioning in healthy people is maintained to very late years in the great majority of people—80 percent or more—without any measurable deterioration.

In the area of dementia, which is a very high priority with this Institute, research has continued to advance. Some of the work done in our intramural laboratories in the NIH clinical center with the PET—position emission tomography— scanner, shows again that the normal brain of the older person has glucose metabolism at the same rate as young brains. There is no decline in metabolic rate. But there are striking changes in the Alzheimer's disease patients. Other recent work shows that in animals, brain tissue can be transplanted successfully to restore function. One preliminary report we have just received bears evidence that antibodies to certain constituents of spinal fluid in patients with Alzheimer's disease are not present or do not react with constituents in the spinal fluid of normal people. So we begin to have some evidence for diagnostic clues.

## NIA PRIORITIES

I would be glad to cite and go into further detail about recent accomplishments, but wanted to comment very briefly on the areas of high priority to the Institute in the coming year. My own highest priority is in the area of training, to enhance and increase training and development of academic leadership and research in aging.

We have prepared a report, at the request of the House Appropriations Committee, on a plan to enhance training, which covers various areas of the Public Health Service. I would like to leave a copy here. It has already been presented to the House Appropriations Committee at their request. This report documents the extensive need for more people to take leadership in this field, summarizes current activity and suggests a number of innovative ways in which we can expand our training efforts.

Some of our other high priority areas include, first of all, Alzheimer's disease in all its aspects. I might just mention that in the response to the action of your committee and the House committee to designate $3.5 million for five centers of research in Alzheimer's disease, we have had 22 very good applications, indicating the opportunity and interest in this field.

Second, we are eager to expand our support of work in molecular biology. There are various aspects of this field which are very relevant to aging itself, the genetics of aging, and to the genetics of some of the common diseases in older people. Several Nobel laureates supported by the NIA are now entering this field of molecular biology research, we're glad to say, but it certainly is an area that we want to expand.

Third, we are anxious to examine in much more depth the characteristics of the population over age 85. As already mentioned, this is the most rapidly growing population. We want to look at all aspects of the needs of these people and how we can maintain health and effective functioning. I might just mention parenthetically that we also conduct demographic and immigration studies related to older people. One recent report shows evidence of considerable increase of reverse immigration from the southern beaches back north and into the Midwest of people—older people who at first moved down there for their later years are apparently changing their minds.

The final area of research emphasis is an opportunity that deals with geriatric research on common important disabilities of older people, in addition to Alzheimer's disease, such as the problem of urinary incontinence. Dr Wyngaarden yesterday referred to clinical trial support we are undertaking, along with the Division of Nursing, on management of urinary incontinence. Other important areas include problems of mobility, falls, and resulting hip fractures; the study of systolic hypertension in the elderly in collaboration with the National Heart, Lung, and Blood Institute; and studies on osteoarthritis with the National Institure on Arthritis, Diabetes, Digestive and Kidney Diseases. A number of these conditions contribute enormously to the cost of care in older people. The cost of hip fractures alone is estimated at about $2 billion a year and Alzheimer's disease at about $30 billion a year. We are currently investing perhaps one-tenth of 1 percent of the current cost of these problems in research related to the causes and possible treatment of them. We feel we have a lot we can contribute directly to health and comfort, as well as to identify the causes of geriatric problems.

Our budget request for fiscal year 1985 is $117,390,000, an increase of $2.47 million. I'll be glad to answer questions.

### POPULATION OVER AGE 65

Senator WEICKER. What were the statistics again that Dr. Kupfer mentioned on population over 65?

Dr. WILLIAMS. The population over 65 will double by the year 2020. That's during the lifetime of virtually everybody in this room. The population over 85 will almost double by about the year 2000. This is almost a 100-percent increase between now and the year 2000 for those over 85.

### HEALTH COSTS OF THE ELDERLY

Senator WEICKER. In terms of those problems which associate with the elderly and, using the criteria, let's say, of costs—the economic cost—you say Alzheimer's disease is at what figure?

Dr. WILLIAMS. It is presently estimated at around $30 billion a year of health care costs in this country.

Senator WEICKER. Is that the top one on the list, or is there something else?

Dr. WILLIAMS. That's the highest for older people.

Senator WEICKER. What's next?

Dr. WILLIAMS. One of the very specific ones I cited earlier is hip fractures, which is almost entirely a disease of old people. Hip fractures cost an estimated $2 billion a year. I would also be glad to provide estimates for such things as heart disease and cancer in older people.

[The information follows:]

### COST OF HEART DISEASE AND CANCER IN THE ELDERLY

According to statistics provided by the National Center for Health Statistics, the health cost of heart disease in the elderly was estimated at approximately $8.2 billion in fiscal year 1980. For the same year, the estimated cost for all neoplasms was about $5.3 billion, including an estimated $4.7 million for nursing home care. Another problem of extreme importance to the elderly is urinary incontinence. The estimated annual cost of nursing home care for this problem ranges between $5 million and $1 billion.

### MAJOR INSTITUTE ACTIVITIES

Senator WEICKER. Now what do you look upon in the coming year? What will be the two principal activities of your Institute? What would they be, if I asked that question?

Dr. WILLIAMS. I would say the principal activities or the principal areas of concentration are on opportunities for increased training and for research in dementia.

PREPARATION FOR THE FUTURE

Senator WEICKER. Do you feel that we're making adequate preparation as a society for this staggering situation that's going to occur here within the next several decades?

Dr. WILLIAMS. I'd have to say I don't think we are making adequate preparations yet. I think we have been moving in that direction, but the concerns of the society are enormous. Again, in the field of providing teachers for the professionals in all fields, we have something on the order of 10 percent of the numbers we need just to train future professionals in related fields and to conduct research.

Senator WEICKER. Just in my legislative year, I have seen the inadequacy of our preparation here by virtue of the fact that we went through a period of time where, in effect, old people were dumped into mental institutions and we graduated to nursing homes, as you know. I just don't see any plan here for the future. To some extent, can we see a return to the home and the family taking care? We have seen the hospice movement. With the figures we're dealing with, who is on top of the whole thing? If we look at the Government as a whole, who is on top of this problem?

Dr. WILLIAMS. There are a number of different coordinating efforts—collaborating efforts. We have an interagency ad hoc committee on research in aging, which was set up as an outgrowth of the charter for this Institute which does bring together the research interests to try to coordinate and collaborate in developing the research aspects.

Senator WEICKER. Has anybody issued a report as to what's going to be required in the year 2000? In the year 2020? In terms of care facilities? I mean the whole range. Is there a report out there as to what is going to be—what's going to have to be in place in this Nation to meet the needs of this population?

Dr. WILLIAMS. There are several reports. There are several careful studies of the demography and the health dependency needs that are occurring. Some of these have been prepared by our own epidemiology section and we could provide these. Then there are figures from the census and the National Center for Health Statistics. All of these add up to an estimate that by the year 2000—that's 16 years from now—if we continue our present practices, we will be needing about 30 to 50 percent more nursing home beds than we have now and about 30 to 50 percent more acute hospital beds than we have now, just to provide for the needs of the elderly population.

No one wants that to happen, and I think there are two ways we can address that issue. One is to go as far as possible in expanding home support services and minimize institutional care. The other is what we can accomplish by research and treatment. In the field of urinary incontinence, for example, which is the second highest cost of admission to nursing homes after dementia, we found that probably 70 to 80 percent of people with urinary incontinence can have this condition managed or treated and controlled. There are real opportunities to decrease the burden of care through research and effective treatment. My view is, we can make a lot of progress through further research and through using what we already know more completely. But it is a huge challenge.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. OK. Thank you very much, Doctor. There are further questions for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the Fiscal 1985 NIH budget -- small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: The NIA has considerable input during the initial stages of the budget formulation process. The first concern in this process is development of a commitment base, to assure that all ongoing research will be adequately supported in the coming year and that there will be sufficient funds for administrative support, supplies, equipment, etc. The preliminary budget submission made to NIH by the NIA is, in effect, a professional judgment budget. It contains not only sufficient funds for currently ongoing research, but also includes funds for the NIA share of competing research project grants and areas of research to which NIA would like to give added emphasis. At each level of the review process -- NIH, PHS, DHHS, OMB -- the preliminary budget estimate is adjusted in accordance with priorities and policies held by that level. These adjustments are generally downward, based on the broader scope at which each level functions, as the budget approaches completion. At each point in the review process, the NIH as a whole can appeal any decision made at a higher level. In sum, while the final total dollars are determined by OMB, there is a substantial amount of negotiation before that figure is arrived at.

### IMPACT OF FY 1985 BUDGET REQUEST

Question: What is the impact of the budget request on your Institute, and what will it do the scientific momentum you are trying to maintain?

Answer: The FY 1985 NIA budget is, overall, 2.2% above the FY 1984 Appropriation. The major portion of this increase is devoted to support of research project grants with a small increase provided for 9 additional full-time equivalent trainees. The remainder of the NIA budget is funded either at or slightly above FY 1984 funding levels, with the exception of Research Management and Support, which declines by $90,000. While this is essentially a level budget, an additional 10 new and competing grants will be supported. Certain high priority research, such as that in the field of Alzheimer disease and other dementias of aging, will be funded at FY 1984 levels. Other research which is of somewhat less priority, will decline. The contracts mechanism, for example, is stable from FY 1984 to FY 1985. The clinical trial on systolic hypertension in the elderly, currently supported with the National Heart, Lung, and Blood Institute, will consequently be supported at a lower funding level in FY 1985 than originally planned.

Question: To what extent will your new and continuation grants be funded below full cost levels -- and what important research will be delayed or eliminated as a result?

Answer: In FY 1985, noncompeting continuating grants will be negotiated downward by about 6%, while competing awards will be cut by around 3%. While the FY 1985 budget request will prevent expansion and delay new initiatives, the downward negotiations themselves are not expected to affect funded research.

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84? What will this do to your efforts to translate the results of basic research into prevention and treatment?

Answer: The centers the NIA is supporting in FY 1984 will cost approximately the same in FY 1985. The centers which will be most involved in translating the result of basic research into prevention and treatment, i.e., the Alzheimer disease research centers for which we expect to initiate funding in FY 1984, will be able to continue in FY 1985.

Question: The overall NIH budget proposes a cutback in research training. What is the impact on your Institute and what will be the impact on your area of biomedical research in the future?

Answer: Within the NIA's overall training effort, the research careers program is a vital part. The NIA will experience a slight reduction under the research career award program, and gains 9 full-time equivalent trainees under the National Research Service Award program. In the shortrun, therefore, the NIA is not unduly affected.

## CURRENT SERVICES ESTIMATE

Question: How much additional funding above the budget would be required in Fiscal 1985 to maintain your Institute at the same level of effort as in Fiscal 1984?

Answer: To maintain the same level of effort in FY 1985, the Institute would require an additional $4,685,000. This amount would allow the Institute to fund the competing and noncompeting research project grants at approximately the FY 1984 level of effort, but would provide for only 120 competing awards, the same number as in FY 1984; this would be 10 fewer than are currently contained in the President's Budget.

## FTE REDUCTION

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Answer: The NIA share of the overall NIH reducton is 16 FTEs. The NIA will be taking these reductions in the Other Than Full-Time Permanent category. Since most of these positions are located in the intramural research program, the majority of the reduction will necessarily be taken in this program area. The remainder will come from the Research Management and Support activity. The impact of these reductions on NIA programs is difficult to assess. The Institute will make every effort to implement the reductions in a way that will minimize the impact on research in progress and on the effective management of the organization.

## ALZHEIMER DISEASE

Question: I think Congress has sent a strong signal of its desire that the research effort on Alzheimer's Disease move into high gear. In Fiscal 1984 we are providing $32 million to NIH for this effort -- a $10 million increase over the previous year. What progress are we making in the effort to identify the cause or causes of this disease as well as the possible treatment?

Answer: Research on Alzheimer disease, the most devastating disease of the aged, has shown that memory dysfunction, the hallmark of this disease, is associated with a deficit in the brain's ability to make the chemicals necessary for cell-to-cell communication. More recently, it has been shown that, in some parts of the brain, nerve cells die in a selective manner. These latest findings raise the possibility that the neurochemical deficits may actually be the result of cell death.

The question of why brain cells die in specific locations within the brain is another area where considerable progress has been made. Five short years ago, very little was known about this problem; now, there are several very promising avenues of research underway. Recent findings include: (1) The possibility that nerve cells die because of the presence of abnormal, insoluble proteins, known as neurofibrillary tangles. These could actually pose a physical blockage within the cell. (2) There is work underway exploring the possible links between the presence of aluminum and the formation of these abnormal proteins. Also, an enzyme has been identified which helps with the synthesis of these abnormal proteins. (3) It has also been shown that in Alzheimer disease there is a deficiency in an enzyme which plays an important role in converting sugar into energy. The deficiency in this enzyme may also contribute to cell death.

Research supported by the National Institute on Aging has shown that, contrary to previously held views, brain cells in aged animals and, more importantly, in healthy normal aged individuals can continue to grow and make new connections. In dementing disorders of the aged, such as Alzheimer's disease, ability of the brain to form new connections is absent. Recent research with nerve growth factors and cell regeneration has shown that in old animals with specific neurotransmitter deficiencies, it is possible to restore normal brain functioning by transplanting normal brain cells. The exciting finding is that nerve cell transplants survive and become functional in old brains. In the future, there is considerable work to be done in this area, but this is a very promising area because we might learn more about the chemistry of nerve repair and be able to apply these techniques for treatment of Alzheimer disease.

Studies of how memory is affected will prove useful as a means of diagnosing Alzheimer's disease or monitoring the progress of the disease. Loss of memory is the first, the most obvious, and ultimately, the most debilitating symptom of Alzheimer's disease. Much research on the disease has focused on patients' progressive loss of episodic memory, e.g., memory for recalling specific events, names, faces, and places. It appears, however, that certain pieces of memory remain intact even when Alzheimer's disease strikes.

There is suggestive evidence that caregivers' attitudes, behaviors, and interactions either aggravate or lessen the occurrence of cognitive and behavioral deficits associated with Alzheimer's disease. The use of socio-behavioral strategies and planned environmental settings seem to alleviate some secondary and tertiary symptoms of Alzheimer's disease, helping Alzheimer's patients to function at optimal levels and reducing the burdens of caregiving.

Future research is being encouraged on several social and behavioral aspects of Alzheimer's disease: the availability of family members and informal supports to care for Alzheimer's patients; the role of families and informal caregivers in the perception of and response to Alzheimer's disease symptoms; the influence of family structure and functioning on the onset and/or exacerbation of Alzheimer's disease symptoms; the burden of Alzheimer's disease on the family and other caregivers; and informal and formal resources for helping Alzheimer's patients and their caregivers.

Question: What is the significance of your work on an infectious agent known as a "prion"? I note you say that this work could lead to a "major breakthrough" in understanding Alzheimer's as well as other degenerative diseases.

Answer: The possibility that Alzheimer disease is caused by a slow-acting viral agent presents one of the most exciting scientific leads about the origins of this disease. Recent findings have suggested that such a slow-acting infectious agent known as a prion has similar structural and biochemical characteristics to amyloids. Amyloid, which is a protein which accumulates outside the cell in various organs and tissue of the body, has been associated with not only Alzheimer disease but other degenerating conditions. The possible link between an infectious agent and amyloid is an important discovery because it may lead to better insight about the mechanisms of the degenerative processes in a number of the diseases of the aged.

Question: While we provided aging with a $6.6 million increase in funding for Alzheimer's research in Fiscal 1984, your budget would increase Fiscal 1985 funding by only $321,000. What happens to the momentum of your research under a standstill budget?

Answer: It takes a considerable amount of time and effort to mobilize the interest of the scientific community in an emerging area of research such as Alzheimer disease. On the average, it takes one to three years to develop a viable research proposal. It has taken the National Institute on Aging five years to attract some of the brightest and most capable neuroscientists to this area of research.

The scientific opportunities concerning Alzheimer disease have captured the attention of a broad spectrum of the scientific community involving such disciplines as neurology, neuroscience, psychology, neuropathology, immunology, medicine, endocrinology, sociology and many others. Our Extramural Program Staff are bombarded with an ever increasing number of inquiries from the scientific community concerning how they can use their particular scientific skills and expertise to solve specific problems in Alzheimer disease. Through publications in the scientific literature, and the public media, the concern expressed by Congress and, most importantly, the work of such groups as ADRDA has mobilized the scientific community. Therefore, if we are to capitalize on the enthusiasm of the scientists and their willingness to apply their modern scientific skills to solve this problem, we should plan on a systematic and sustained expansion of resources to be devoted to this problem. In FY 1985 the NIA will increase its funding for Alzheimer disease by approximately 4.3 percent.

## ALZHEIMER CENTERS

Question: In our fiscal 1984 Labor-HHS bill Congress provided for $3.5 million for the establishment of 5 specialzied research centers on Alzheimer's disease. What have you done to implement this Congressional directive and when will the Centers be established?

Answer: The NIA received 32 Letters of Intent from some of the most eminent medical centers throughout the country concerning the establishment of Alzheimer Disease Research Centers. Of these, 22 institutions have submitted formal applications. The NIA expects to review these proposals in the months of June and July, and make the awards before the end of September. The centers are expected to be fully operational by early calendar 1985.

Question: To what extent will applicants be required to have a track record of research on Alzheimer's in order to compete successfully for designation as a center?

Answer: It will be important for an applicant institution to have had a proven history of research on Alzheimer disease. However, the guidelines for the Alzheimer Disease Research Center applications were structured so that any institution, regardless of its past history, that has the qualifications for a center of scientific excellence could effectively compete for a center grant.

Question: How much training will the Centers do and where will they get funding for it?

Answer: Research, training, and education are the three principle functions each Center is expected to fulfill. The center grant will provide funds for coordination of training activities associated with Centers. The stipends for the training are expected to come from the regular NIH training grants awarded to the institutions associated with the Centers.

Question: How much are you allocating to the Centers in Fiscal 1985 and will this be sufficient?

Answer: The Alzheimer centers will be supported in FY 1985 at approximately the same level as FY 1984, that is, at a total of about $3,500,000. It is anticipated that this will be sufficient.

## THE AGING PROCESS

Question: The Subcommittee continues to be interested in your research into the aging process itself. Where does it presently stand -- and what are you finding about the possibility of extending life beyond current life expectancy limits?

Answer: Basic research on the nature of aging processes is currently being supported by the NIA on the molecular, cellular, organ and organism levels. Inasmuch as research support for these areas only began in earnest in the late 1970's it is not surprising that this research is in the earliest phases. Nevertheless, there are many exciting insights into the nature of aging. For example, from the work of our grantees we now know that there are substantial changes in the genome with aging. Specific gene sequences are lost from chromosomes and accumulate outside chromosomes. At present it is difficult to conjecture on whether this research will result in the extention of human lifespan.

Question: To what extent does your Institute look ahead and analyze the problems of a society with an expanding older population?

Answer: The NIA is deeply concerned with the increasing absolute and relative numbers of older Americans. There are important social as well as medical problems inherent in this trend. As our population ages, the burden of disease and disability will shift from acute diseases to chronic diseases. In response to this trend, the NIA has launched many initiatives related to understanding the mechanisms of these disorders. These include the development of Alzheimer Disease Research Centers and a co-operative agreement with the Division on Nursing to support clinical trials on Behavioral Therapies for Urinary Incontinence. In addition, I have led a task force to examine the needs for geriatric manpower to respond to an older America.

NIA's Behavioral Sciences Research (BSR) program supports research on the growth and composition of the older population and on the methodology of forecasting life expectancy, active life expectancy, and needs of the elderly population. Analyses have shown that the recent increases in life expectancy at the oldest ages are likely to continue into the future, and that the segment of the population over age 85 is likely to be the fastest growing segment of the population over at least the next decade. The population over age 85, who are heavy users of health care and related services, has been identified as a high priority area for the NIA. There is a need for more data on the oldest segment of the population.

The BSR program also supports studies on the impact of the changing age structure on the social, economic and cultural characteristics of society, including simulation studies of these effects. For example, the geographical distribution of the growing older population has an important impact on the local demand for services. While thousands of retirees move from the Northeast and Midwest to, for example Florida, each year, a new analysis of the data from 1970-80 shows that a small but significant number of much older and poorer individuals have been migrating in the opposite direction, thus adding to requirements of support services in Northern cities like New York. However, much more research needs to be done if we are to be prepared to deal with the problems (and meet the opportunities) that an expanding older population will bring. In particular, we need more basic studies whose results can be used in the long range planning for the income, housing, health and other related care, and needs of the elderly, and especially of the oldest old. Thus, it is especially important to be able to predict the numbers, composition, the health status, and the needs of the future elderly population.

Since health costs and other care related costs for the very old are expanding at a rapid rate, it is imperative to invest in research which could lead to a slowing in the growth rate of these costs. New initiatives such as the proposed clinical trials on behavioral treatments for urinary incontinence or research on the development of programs to reduce the number of falls among the elderly could have a substantial impact on the health and care related costs associated with urinary incontinence and hip fractures.

It is, however, not enough to reduce health costs. There must also be research on how to increase the productive contribution that healthy older people can make to society. Toward this end, the BSR program also supports studies of the roles of older people; the relation of age to laws and to differential opportunities for productivity, income, work, education, political participation, and long-term care; age-based conflict and age-integration vs. age-segregation; cross-cultural and cross-temporal variabilities; and the influence of sex, race and ethnicity, and social class on the roles and opportunities open to adults from the middle to the oldest ages. Studies are also sought on how the changing age structure of the population is affecting societal institutions such as the family and work organizations as well as health care institutions.

## RESEARCH OPPORTUNITIES

Question: What research opportunities on the aging process are available to you now that you cannot take advantage of because your budget is too low?

Answer: There are a number of research opportunities relating to obtaining a better understanding of aging processes that could be expanded or initiated if more funds were available. There are always more initiatives worthy of funding than resources.

Advancements in recombinant DNA technology have greatly increased the power of biologists to examine changes in gene structure and function. It is now timely to apply this technology to gain insight into the mechanisms of aging at the level of the genome. This can be accomplished through an extramural funding initiative, a set aside of funds for research in this area, and intramurally by establising resources in molecular biology.

By developing biomarkers of aging, it is possible to gain an understanding of aging processes as opposed to disease processes. In addition these biomarkers of aging can be utilized to examine the efficacy of specific interventions that may slow or arrest specific aging processes. An example of a biomarker of aging is the decline in function of certain immune cell populations. Planned contracts to support the development of biomarkers may not be able to be initiated under present FY 1985 projections.

There are many approved meritorious research proposals on degenerative processes responsible for morbidity and mortality in the elderly which could be funded. One such research area is the relationship of age-related impairments in immune function to the greatly increased risk of infections in the elderly, a major cause of mortality which is potentially preventible through immunologic intervention.

Another research area is the relationship of age-related changes in cartilage and other tissues of joints to osteoarthritis. It is crucial to understand these relationships if we are to understand why some older people develop severe arthritis and some do not. This knowledge could in turn lead to means of preventing osteoarthritis and its disabling consequences.

A third such research area is the development of effective treatments for urinary incontinence, a major cause of institutionalization of older persons in nursing homes. The NIA has committed support for clinical trials of promising new treatments, but constraints on funds have limited the number of such treatments to be tested.

There has also been insufficient research on the causes of falls and injuries resulting from falls, particularly hip fracture, in the elderly. Injuries resulting from falls are major causes of morbidity and mortality often resulting in the death or disability of a previously healthy older person. Preliminary data from studies supported by NIA indicates that a high proportion of falls and fall injuries are preventible, but there is a need for more research on the basic causes of falls in the elderly and tests of prevention strategies.

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## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### CLINICAL TRIALS

Question: Dr. Williams, Dr. Kupfer's prepared testimony indicated that the Eye Institute had initiated a clinical trial to explore means of preventing or slowing the progression of aging-related maculopathy. Did your Institute participate in the design of this clinical trial?

Answer: No, we did not participate in the design of this clinical trial.

Question: Does your Institute play a major rate in supporting research into the aging of the vision process and, if so, how do you decide whether a research project in this area should be supported by the Eye Institute or the Institute on Aging?

Answer: The National Institute on Aging complements the National Eye Institute in supporting research into the visual process. The Behavioral Sciences Research program of NIA supports research projects designed to examine the nature of age-related differences and changes in visual perception, as these relate to the effective functioning of older people in everyday life. This initiative is coordinated with related programs in the National Eye Institute and emphasizes normal aging and visual perception. Grant proposals in this area of study typically are given a dual assignment to both the NIA and NEI. The final funding decisions are made following a consultation between the staff of the two instituties. If the aging process is the crucial variable in a project, it is typically assigned to the NIA.

### ALZHEIMER DISEASE

Question: Dr. Williams, last year for the record I asked you to differentiate your work on Alzheimer's disease from the research supported by the National Institute of Neurological and Communicative Disorders and Stroke. Although you indicated you were the lead agency for the attack on Alzheimer's disease and that you expected to devote 11 percent of your 1984 budget to the disease, you did not indicate how it was decided whether your institute or some other supported a particular research initiative in this area. Could you tell us how these decisions are made?

Answer: Whenever there is an overlap of program interest among the institutes at NIH, carefully thoughtout and defined guidelines are developed by the interested institutes. Such guidelines define the individual programs and are used by the Division of Research Grants to assign applications. In 1980, the Secretary, DHHS, designated the NIA as the lead organization in the initiative on Senile dementia of the Alzheimer's type. In 1983, the NIA updated the National Plan for Research on Aging, and submitted it to Secretary Heckler. Both this updated Research Plan and its predecessor (1975) identified the Neuroscience of Aging and research on dementing disorders of aging such as Alzheimer's disease as high priority program areas for NIA. Since 1977, the Institute has devoted a significant proportion of both its extramural and intramural resources to this program area, and currently provides over half of all the Federal support for research on Alzheimer disease.

At present, NIA's Neuroscience of Aging Program and its portfolio of research on Alzheimer's disease represents one of the most comprehensive and well developed programs that is exclusively devoted to understanding the aging brain and nervous system.

The essential difference between NIA research on Alzheimer disease and that of NINCDS is that NIA focuses on the disease within the context of the aging process as a whole. NIA's program interest can be distinguished from that of other Institutes by a number of key elements. Firstly, the NIA studies aging as a process. The aged as subjects, and aging-related changes as phenomena, are primary interests to NIA. Secondly, the NIA program is concerned with age-related changes in the brain or nervous system in the context of other age-related physiological or homeostatic regulator changes, e.g., endocrine, dietary, immune, disease states, etc. The NIA is also interested in understanding degenerative processes or pathological changes in the aging brain in the context of understanding or comparing such events with normal age-related changes. In terms of practical applications, the NIA is concerned with the burden of care faced by family members of Alzheimer patients, characteristics or factors which help or hinder family support of such patients against a background, of NIA-supported research on family relations in general with aging persons.

Of the many brain impairments in the aged, decreased cognitive functioning is generally accepted to be the most consistent and serious problem. In its most severe form, cognitive impairment is the hallmark of senile dementia or Alzheimer's disease. Therefore, brain phenomena related to cognitive impairment or brain changes related to memory-decline is one of the principal focuses of NIA's Neuroscience of Aging Program.

An important related research question, relevant to the NIA's program, concerns distinguising structural and biochemical changes of aging in the brain from the changes found in Alzheimer disease.

A number of studies have reported that approximately 10 percent of the elderly population have clinically significant cognitive deficits. The frequency of intellectual impairment is considerably higher among the elderly living in nursing homes; over 50 percent of them, it is estimated, have some form of mental impairment. However we know that cognitive impairment in the elderly, if diagnosed properly, can frequently be cured or ameliorated.

At present there are no specific studies identifying the frequency and cause of reversible cognitive impairments in the elderly. However, from inferential data it is estimated that 10-20 percent of persons 65 and older identified as having intellectual impairment may have reversible brain disorders. This misdiagnosis is an extremely costly error and a tragic waste when it leads to long-term institutionalization. The prospect of several hundred thousand older people mislabled demented, who could have returned to a productive life with appropriate evaluation and treatment, poses a staggering problem for geriatric medicine and the neurobiology of aging. To resolve this challenging problem, the Neuroscience of Aging Program has been designed to address two issues: (a) the need for better diagnostic tools for assessing cognitive impairment or brain failure in the aged; and (b) the need for more scientific knowledge of the mechanisms of brain aging.

## FY 1985 ALZHEIMER DISEASE RESEARCH

Question: Please provide for the record a summary of how much each Institute plans to spend on Alzheimer's disease in Fiscal Year 1985 and what activities will be supported with those funds.

Answer: The following table is submitted for the record.

FY 1985 Alzheimer Research

| Institute | Amount | % of Total Institute Budget |
|---|---|---|
| National Institute on Aging | $19,301,000 | 16.4% |
| National Institute of Neurological and Communitive Disorders and Stroke | 11,230,000 | 3.3% |
| National Institute of Allergy and Infectious Diseases | 1,550,000 | 0.5% |
| Division of Research Resources | 673,000 | 0.1% |

In FY 1985, the National Institute on Aging will continue to support Alzheimer disease research with an emphasis on the causes of Alzheimer disease, early accurate diagnosis, and possible treatments.

At present, there are several promising areas of research concerning the cause of Alzheimer's disease. Among these, Alzheimer's disease is one of the most important. A second important area is the question of why nerve cells die in specific parts of the brain controlling memory function and learning ability. The possibility that an infective agent such as a slow virus or virus-like particles may cause the disease has also attracted wide attention. The role of heavy metals, such as aluminum, in the environment continues to be an area of active research. Work is also under way to study enzymes that are needed by the brain cells for breaking down sugar, and for synthesizing neurotransmitters. The chemistry of how abnormal proteins, which may lead to cell death, are formed in the brain cells of Alzheimer patients is an active and important area of study, as is the question of whether the genetic machinery is involved and what the nature of the defect is. Finally, how the blood brain barrier is damaged in Alzheimer's brains is another area of study.

The development of more accurate, specific and sensitive neuropsychological test batteries is one of the most promising areas of research for early and accurate diagnosis. Nuclear magnetic resonance (NMR) promises to be an effective noninvasive diagnostic technique. Positron Emission Tomography (PET) has already shown some remarkable results in our ability to differentiate the normal brain functioning in healthy, aged people from those with Alzheimer's disease as well as other dementing conditions in old age. The availability of automated biochemical analytical instrumentation will soon enable us to measure accurately the presence or absence of various metabolites in the blood, cerebrospinal fluid and the brain. As we understand better the specific difference in the biological markers of normal aging brain and those with degenerative dementing diseases, such instrumentation and technologies will enable us to diagnose Alzheimer's disease more accurately and earlier in the course of the disease. For example, preliminary studies from an NIA supported project indicates that the ratio of choline concentration (an ingredient necessary for the synthesis of the neurotransmitter acetycholine) in the red blood cells and the plasma is different in Alzheimer's patients compared to normal, healthy, aged individuals. If this work is successfully replicated by others, it may provide us a very easy to administer, inexpensive and accurate diagnostic tool. We want to emphasize that there is considerable work to be done in this area of research; the work being cited is an example of the many possibilities.

Research on the treatment of Alzheimer's disease is a very difficult area of work because we do not know whether we are dealing with a simple disease or many diseases with different patterns of brain changes. Nor do we know whether brain cells merely malfunction or die, or both. Because of the uncertainty in the diagnosis of Alzheimer's disease, the results of research or treatment is a mixture of successes and failures. Nevertheless, in spite of these difficulties, work is underway in this realm. With respect to treatment, some of the drugs which increase the ability of nerve cells to synthesize and release more neurotransmitters or inhibit the breakdown of these substances appear to provide some promise for ameliorating the symptoms of Alzheimer's disease in the early stages. In the very early experimental stages, work is underway with brain transplant techniques using animal models. Such studies have shown that it is possible to ameliorate brain dysfunctioning related to deficits of specific neurotransmitters. Such work has a considerable way to go before it can be safely and ethically used in human subjects, but, nevertheless, it is a promising area of research for the treatment of Alzheimer's disease.

NIA-supported projects indicate that even in old age the nerve cells in the brain still possess the ability to grow and regenerate. In Alzheimer's disease, it appears that the brain loses this ability. If through further research we can find the biochemical or endocrine factor which enables brain cells to repair or regenerate, then we will have an extremely powerfull tool for treating this disease.

Behavioral sciences aspects of Alzheimer's disease are also being investigated. For example, one newly funded study will compare the natural histories of early Alzheimer's patients and normal aged people. Questions to be addressed include the longitudinal course of Alzheimer's disease among the noninstitutionalized; the determinants of well-being among community-resident Alzheimer's subjects; person-environment congruence and coping behavior in the Alzheimer's patients; relationship of neuroendocrine responses to person-environment congruence; and the interrelationships among depression and cognitive dysfunction.

Future research is being encouraged on several social and behavioral aspects of Alzheimer's disease: the availability of family members and informal supports to care for Alzheimer's patients; the role of families and informal caregivers in the perception of and response to Alzheimer's disease symptoms; the influence of family structure and functioning on the onset and/or exacerbation of Alzheimer's disease symptoms; the burden of Alzheimer's disease on the family and other caregivers; and informal and formal resources for helping Alzheimer's patients and their caregivers.

In addition to collaborative research, both intramural and extramural, done with the NIA, both NINCDS and NIAID support programs of research related to Alzheimer disease. NINCDS projects over the past several years have included an interagency agreement with NIMH to provide data on the incidence, prevalence, history and progression of Alzheimer disease, and the economic and social impact of Alzheimer disease as it affects individuals, their families, and friends; a study on selective destruction of nerve cells in Alzheimer dementia; a study of metal deposits in the brains of dementia victims; and an attempt to characterize the agent responsible for the development of scrapie, a central nervous system disease affecting sheep which has provided a model for the study of dementing disorders in humans. Other areas of endeavor include research on the structural abnormalities which characterize Alzheimer disease; the biochemical alterations of the disorder; risk factors which might lead to the development of dementia; and the chemistry of immune complexes in Alzheimer disease. NIAID is conducting research on the biology and epidemiology of viruses associated with persistent and latent infections, notably the scrapie virus.

## DIVISION OF RESEARCH RESOURCES

**STATEMENT OF DR. BETTY H. PICKETT, DIRECTOR**

**ACCOMPANIED BY:**

- **DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **DR. JAMES F. O'DONNELL, DEPUTY DIRECTOR**
- **ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. Next we shall hear from the Division of Research Resources, which has responsibility for providing the sophisticated equipment and other facilities needed by biomedical researchers. The Division also funds projects aimed at the most effective use of animals in research and supports the seven national primate research centers. The request for the Division is almost $246 million. This is $3 million above the fiscal 1984 appropriation level.

Dr. Betty Pickett, Director of Research Resources, is with us today to testify on behalf of the Division's budget request. We welcome you, Dr. Pickett. And I also want you to know in the room that I got reminded in a rather forceful fashion, when one of my general statements referred to the gentlemen that were in charge of the various institutes of the National Institutes of Health that Dr. Kirschstein and Dr. Bick and you, Dr. Pickett, that there are some ladies that are in that category and I should not restrict my comments to gentlemen that run the institutes, and so I apologize to you at the same time that I welcome you.

Dr. PICKETT. Your apology is warmly received.

[The statement follows:]

## STATEMENT OF DR. BETTY H. PICKETT

I am pleased to present the 1985 budget request for the Division of Research Resources (DRR).

The Division was established in 1962 to provide for the development, support, and administration of research resources programs. The efforts of many biomedical researchers who receive support from the categorical institutes of the NIH rely heavily on the research environments, facilities, and sophisticated instrumentation provided by the Division. In fact, more than 5,100 NIH research grants, with a total cost in excess of $620 million, are awarded annually to institutions whose research investigators use the resources provided by DRR.

The Division comprises five distinct program activities. The Clinical Research Program provides for development and maintenance of the General Clinical Research Centers, specialized clinical research environments within academic medical centers. These centers provide the environment for investigations which can lead to major medical advances in the prevention, diagnosis, and treatment of disease. Within the centers, clinical applications of laboratory findings--such as development of innovative implantable devices, new drugs and surgical techniques--can be properly evaluated for their ability to improve human health.

Research conducted within the centers contributes very importantly to major NIH research initiatives, including immunology, cancer, nutrition, diabetes, digestive diseases, prevention, genetics, and maternal and child health. Recently, an NIH Consensus Development Panel concluded that liver transplantation is a useful therapy in end-stage liver disease. Much of the research on liver transplantation in this country has been conducted in GCRCs. The use of the immunosuppressive drug, Cyclosporin, in liver transplantation was also pioneered in a GCRC. Use of this drug is credited with increased survival rate of liver transplant patients.

The Biotechnology Resources Program provides investigators access to the latest technological applications of the physical sciences, mathematics, and engineering. The biotechnology resource centers are designed to provide: advanced instrumentation where the instrument or supporting technology is highly experimental; research on the instrument or on the development of new research techniques which require its use; and training in the application of the technology or the use of the instrument. The program provides support for large-scale computer systems and biochemical and biophysical analytical instruments, such as nuclear magnetic resonance spectrometers and million-volt electron microscopes. These facilities are provided on a shared basis (national or regional) to overcome constraints of high cost, technical complexity, or scarcity.

In 1985, the Division plans to emphasize support for the development and use of in vivo high field nuclear magnetic resonance (NMR) spectroscopy in biomedical research. In vivo NMR spectroscopy, when used to measure metabolic changes, is expected to serve both basic and clinical researchers.

Cellular organization, structure and function can now be studied at levels not previously possible, as a result of more powerful image analysis techniques and the use of intermediate voltage electron microscopes. Complementing the very high voltage microscopes already supported by the Division, these newer instruments will be very useful in studies of whole cells, proteins, and other cellular components.

DRR's national computer network (the PROPHET System) has been providing biomedical scientists with a comprehensive set of computer tools. PROPHET's capabilities now include graphics and statistical analysis, curve fitting, mathematical modeling and simulation, methods of modeling molecules, and tools for analyzing the sequences of RNA, DNA and proteins. Via PROPHET's national telecommunications system, data may be entered, studied, and analyzed from any location within the country promoting research collaboration among scientists located at widely separated sites. Because the system has now been in operation for 13 years, a major update is necessary. In 1985 we plan a major project to redesign and reequip PROPHET.

DRR's Laboratory Animal Sciences and Primate Research program supports the seven Regional Primate Research Centers, and a variety of other Laboratory Animal Sciences resources. Research on diseases affecting nonhuman primates and other research animals advances our understanding of similar diseases in man, and improves our ability to care for research animals. A key example is the investigation into spontaneously occurring cases of Simian Acquired Immunodeficiency Syndrome (SAIDS) at two Regional Primate Research Centers. Immunological, pathological, and virological studies have confirmed several basic similarities of this syndrome to human AIDS. Consequently, SAIDS may serve as a valuable model system which may lead to improved understanding of the causes, pathogenesis, and transmission of human AIDS.

The Diagnostic Laboratories make possible improved laboratory animal health programs through research on diseases of laboratory animals and elucidation of new animal models of human disease. The laboratories also serve as resources for research and research training. Primate breeding colonies, a Primate Supply Information Clearinghouse, and related activities help assure a stable supply of needed primate species. To date, DRR-supported breeding colonies have helped to meet demands for rhesus and other species.

In 1984, we are beginning to address needs for repairs and renovations in the Primate Research Centers. Within the request, $1,000,000 will be used for the continuation of these activities.

With the assistance of the National Academy of Sciences, a Biomedical Research Models Development (BRMD) Activity has been launched with the purpose of exploring the use of cell systems, lower organisms, and nonbiological systems as models in biomedical research sponsored by the NIH. Such model systems may provide cost-effective resources to the research community if they serve as simple, effective, or efficient representations of complex biological phenomena.

In 1985, the Division will award $47,417,000 in Biomedical Research Support Grants to an estimated 556 research institutions. These grants allow on-site allocations of research funds for pilot research; interim support and emergency funding; centrally shared facilities and equipment; and support for new investigators and improvement of research skills.

Institutions which receive at least three Public Health Service grants with a total dollar value of at least $200,000 are eligible for a Biomedical Research Support Grant. In 1985 the program will continue to reach the full range of eligible biomedical research institutions, including medical, pharmacy, dental, nursing and graduate schools.

Instrumentation obsolescence and shortage have been identified as severe problems at research institutions. Therefore, the Division initiated the Shared Instrumentation Grant Program in 1982. For 1985, the request is $19,770,000 for the Shared Instrumentation Grant

Program, the same level as in 1984. Since 1982, the Division has made over 200 awards for the purpose of replacing worn out or obsolete equipment, or for the addition of new items. Instruments provided include electron microscopes, mass spectrometers, nuclear magnetic resonance spectrometers, cell sorters and image analysis systems.

Included within the request for the Biomedical Research Support Program is the continuation of the Minority High School Student Research Apprenticeship program. The $1,000,000 requested will provide support for 666 high school students at approximately 270 research institutions throughout the country. The purpose of the awards is to bring high school students into research laboratories during the summer.

For over a decade, DRR's Minority Biomedical Research Support Program has supported awards whose purpose is to expand opportunities for ethnic minorities to pursue careers in biomedical research. Nearly 550 research projects were supported through the MBRS Program in 1983. As a result, more minority students are participating in biomedical research and more have opportunities to pursue careers in research. In addition, institutions with predominantly ethnic minority populations are becoming more proficient in the conduct of biomedical research, because of the institutional support provided by the Division. Important findings have resulted from some of these projects, e.g. the discovery of a possible target for interferon action in the mammalian cell; and information on interactive drug effects, possibly significant in the treatment of hyperkinetic motor disorders.

Within the total available for the Minority Biomedical Research Support (MBRS) Program, up to $1 million will be used specifically to address research equipment and instrumentation needs at MBRS institutions.

Mr. Chairman, our request for Research Resources is $245,728,000, an increase of $3,097,000 over the comparable FY 1984 level. I will be pleased to answer any questions you and the Committee may have.

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## BIOGRAPHY OF DR. BETTY H. PICKETT

Date and Place of Birth: February 15, 1926
Providence, Rhode Island

Marital Status: Married to James McPherson Pickett, 1952

Education:

1945 - A.B. (Psychology) Magna Cum Laude, with high honors in Psychology, Brown University

1947 - Sc.M. (Psychology), Brown University

1949 - Ph.D. (Psychology), Brown University (Thesis: Performance of Conditioned Responses as a Function of Strength of Hunger Drive)

Positions Held:

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| October 1982 - Present | Director, Division of Research Resources |

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| July 1982 - September 1982 | Deputy Director, National Institute of Child Health and Human Development |
| July 1981 - July 1982 | Acting Director, National Institute of Child Health and Human Development |
| July 1979 - July 1981 | Deputy Director, National Institute of Child Health and Human Development |
| January 1979 July 1979 | Deputy Director-Designate, National Institute of Child Health and Human Development |
| June 1977 - January 1979 | Associate Director for Extramural and Collaborative Research Program, National Institute on Aging |
| March 1977 - June 1977 | Associate Director for Extramural and Collaborative Research Program (Designate), National Institute on Aging |
| July 1975 - March 1977 | Acting Director, Division of Extramural Research Programs, National Institute of Mental Health |
| September 1974 - July 1975 | Director, Division of Special Mental Health Programs, National Institute of Mental Health |
| February 1968 - September 1974 | Deputy Director, Division of Extramural Research Programs, National Institute of Mental Health |
| July 1966 - February 1968 | Chief, Cognition and Learning Section, Behavioral Sciences Research Branch, Division of Extramural Research Programs, National Institute of Mental Health |
| August 1963 - July 1966 | Executive Secretary, Research Career Program, National Institute of Mental Health |
| August 1962 - August 1963 | Research Consultant to Mental Health Unit, Region #1, Public Health Service, Department of Health, Education, and Welfare |
| March 1961 - August 1962 | On leave and resident in Stockholm, Sweden (during husband's year of study at Royal Institute of Technology) |
| December 1959 - March 1961 | Executive Secretary, Experimental Psychology Study Section, Division of Research Grants, National Institutes of Health |
| March 1958 - December 1959 | Executive Secretary, Behavioral Sciences Study Section, Division of Research Grants, National Institutes of Health |
| March 1953 - March 1958 | Professional Associate, Psychological Sciences, Bio-Sciences Information Exchange, Smithsonian Institution, Washington, D.C. |
| February 1952 - June 1952 | Lecturer in Psychology, University of Connecticut, Department of Psychology |

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|---|---|
| September 1951 - December 1951 | Assistant Professor, University of Nebraska, Department of Psychology |
| September 1949 - June 1951 | Assistant Professor, University of Minnesota, Duluth Branch, Department of Psychology |

## Membership on Task Forces, Committees:

EEO Counselor, NIMH, 1970-1972

Civil Service Commission Board of Examiners, Health Scientist Administrator Panel, 1970-1976; 1981

Special Assistant to the Director, National Institute of Mental Health, for Women's Action Program, June 1971-1972 (Purpose: To establish the NIMH Women's Council)

National Institute of Mental Health Research Task Force, May 1972 - November 1974, Co-chairperson, Psychology Study Group

Grants Associate Board, Division of Research Grants, National Institutes of Health, 1973-1974; 1978-1980

Director's Research Advisory Group, National Institute of Mental Health, September 1974 - April 1977

Interagency Committee for the Implementation of the Research on Aging Act of 1974, Research and Planning Subcommittee, October 1974 - May 1974

Task Force to Study the Research Program of Saint Elizabeth's Hospital, July 1974 - December 1975 (Task Force Chairperson)

National Institute of Mental Health Outside Work Activities Task Force, March 1976 - June 1976 (Task Force Chairperson)

National Institute on Alcohol Abuse and Alcoholism Task Force on Grants and Contracts to National Organization, June 1976 - December 1976

National Institutes of Health Extramural Associates Program, 1978

Chairman, National Institute of Mental Health Search Committee for Chief, Laboratory of Psychology and Psychopathology, 1978

Member, National Institutes of Health, Search Committee for Associate Director for Administration, 1979

Member, National Institutes of Health, Alcohol, Drug Abuse and Mental Health Administration Interagency Committee on Health and Behavior, 1980

Member, National Cancer Institute Search Committee for Deputy Director, 1980

Member, National Institute of General Medical Sciences Search Committee for Associate Director for Program Activities, 1981

Member, National Institute of Dental Research Search Committee for Director, 1982

Member, Committee on SES/SSS Performance Reviews, 1983

Member, Office for Protection from Research Risks, OD, NIH, Search Committee for Director, 1983

Chairman, Performance Review Board for BID Deputy Directors and Associate Directors, and Bureau Division Directors, 1984

Member, Director's Advisory Performance Review Board, 1984

Societies:

American Psychological Association
Eastern Psychological Association
Psychonomic Society
Association of Women in Science
American Association for the Advancement of Science
Society for Research in Child Development
Academy of Behavioral Medicine
Sigma Delta Omicron, Graduate Women in Science

Honors:

Phi Beta Kappa, 1945
Sigma XI, 1945
University Fellowship, Brown University, 1947-48
Miss Abbott's Alumni Fellowship, Brown University, 1948-49
A.B., Brown University, Magna Cum Laude, high honors in Psychology
DHEW Superior Service Award, 1972
DHEW Distinguished Service Award, 1975
FEW Award for Distinguished Service in Support of Equal Opportunities for Women, 1975
Citation from Graduate School, Brown University, for scientific and professional achievement, 1978
Harold M. Hildreth Award (for distinguished contribution to Psychology in the public service, 1979, American Psychological Association)
Elected Fellow, AAAS, 1981
Recipient of SES Bonus Award for Outstanding Performance, 1981
Recipient of SES Bonus Award for Outstanding Performance, 1982
Recipient of SES Bonus Award for Outstanding Performance, 1983

Research Interests:

Experimental Psychology
Research Administration

Publications:

Kimble, G. A., and Horenstein, Betty R. Reminiscence in motor learning as a function of length of interpolated rest. J. Exp. Psychol., 38, 239-244, 1948.

Schlosberg, H., Duncan, M. C., Daitch, and Horenstein, Betty R. Mating behavior of two live-bearing fish Xiphophorus hellerii and platypoecilus maculatus. Physiol. Zool. XXII, 148-16, 1949.

Horenstein, Betty R. Performance of conditioned responses as a function of strength of hunger drive. J. Comp. Physiol. Psychol., 44, 210-224, 1951

Pickett, J. M., and Pickett, B. H. Communication of speech sounds by a tactual vocoder. J. Speech & Hear. Res., 6, 207-222, 1963.

## SUMMARY STATEMENT

Dr. PICKETT. I am happy to present the President's request for the fiscal 1985 appropriation for the Division of Research Resources. As you know, the Division is now in its 22d year of activity, and it continues to provide resources essential to the conduct of a broad range of today's complex biomedical research. Our full statement provides details, so I will simply highlight the nature of our five programs now.

Starting with the clinical research area, through the general clinical research centers, the Division provides the environment in which much of NIH's extramurally supported clinical research takes place. That research impacts on the NIH initiatives on major diseases and areas such as nutrition, metabolism, immunology, genetics, and so forth. The Division's Biotechnology Research Program makes available instruments using highly advanced technologies for biomedical research on a regional and national basis, including machines such as computers, and tools for biochemical and biophysical analysis of biological materials, including cellular structure. The Laboratory Animal Sciences and Primate Research Program supports centers for the development, study, and breeding of animal models critically needed for the study of human disease, and also supports the seven regional primate centers to which you referred.

The biomedical research support grants, about which we had so much conversation here and in the House last year, provides flexible noncategorical support to 546 institutions which have at least three Public Health Service grants totaling $200,000.

In addition, through the Shared Instrumentation Grant Program, a recently developed and very well received activity, the Division provides funds for both replacement and new items of laboratory equipment. As Dr. Wyngaarden mentioned yesterday, I believe, in answer to a question from you, that program is on target with the goal set for it in a report to the two committees a couple of years ago.

We continue our support through the Minority Biomedical Research Support Program for research activity by faculty and students at institutions which heavily serve U.S. minority populations. We are making a sustained effort to increase the opportunities for developing research careers among minorities, and I should add that included in our effort is a special $1 million initiative specifically for instrument replacement for minority institutions.

Senator WEICKER. How much?

Dr. PICKETT. $1 million, in response to a directive from this committee that a portion of the instrumentation funds be set aside for the institutions serving minorities. With respect to the minority program, I am pleased to report we are beginning to see students who have participated in the Minority Biomedical Research Support Program, now obtaining post doctoral fellowships in laboratories across the country. And I was delighted, on a recent visit to the Meharry Medical College, to learn that one of the graduates has been invited to present a paper at one of this year's prestigious Gordon conferences of biology. That's very special. Others are obtaining faculty positions at majority and minority institutions.

In summary, more than 5,100 NIH research grants, with a total cost in excess of $620 million are awarded annually to institutions whose investigators use resources provided by the Division. Approximately 25 percent of the NIH research grant portfolio thus is facilitated by DRR.

Our request for fiscal year 1985, Mr. Chairman, is $245,728,000, an increase of 1.3 percent, $3,097,000 over fiscal year 1984.

I would be pleased to answer your questions.

## RESEARCH INSTRUMENTATION

Senator WEICKER. Wherever I go among the institutions of higher learning, the big concern relates to—and not just in the medical field, but across the board—the biggest concern relates to equipment, and the fact that it's out of date and worn out. This is obviously especially so in the medical field. Indeed, I think in that speech you made reference to this, Dr. Wyngaarden—the obsolescence of the equipment—and that's very much a concern whenever I sit down and visit the universities.

Now probably a good analogy would be that the roads of this country are all worn out now at the same time as when we had our big push in that area.

How are we at a 2-percent increase going to get this back into the shape that it should be?

Would you cite that as one of your great concerns in the sense of this budget?

Dr. PICKETT. Yes; it is a great concern. This budget provides over $20 million, specifically for instrumentation replacement and purchase. This is for off-the-shelf instrumentation to be used by groups of three or more investigators supported by NIH research grants. In addition, this budget provides $27 million for large instrumentation centers run by the Biotechnology Program: large computers, spectrometers, million volt electron microscopes, et cetera. In addition, the National Institute of General Medical Sciences continues a small program in instrumentation replacement. If I may, I'd like to just give you a little of the history of this effort, since it began in 1982. First of all, the number of applications, after an initial influx of applications and a very small amount of money, has sort of settled down, until the current deadline which has just passed. We have 224 applications pending review right now, requesting $49.1 million. Apparently, the community has finally really cottoned to this program and is telling us what they need, in terms of equipment which is sharable among three or more investigators supported by NIH research grants.

We have a very high approval rate in this program. I should say we estimate that of those 224 applications, around 200 probably will be approved at a cost of approximately $44 million.

In the Shared Instrumentation Grant Program, we have $19,770,000, so we will be able to fund about 42 percent of those approved applications in fiscal 1985. I hope that answers your question.

Senator WEICKER. The figures seem low. I am not familiar with what medical instrumentation costs, but I imagine it is expensive stuff. Isn't your profession one of those that use those large cray computers? What does one of those things run?

Dr. PICKETT. $9 million. We haven't been asked for one of those. Our program is on a somewhat more modest basis, with guidelines that say you may ask for—or three of you may ask for—equipment costing between $100,000 and $300,000. If you wish to buy something that costs more than $300,000, we will be willing to consider giving you the $300,000, if you'll tell us how you are going to get the rest of it. I suppose someone could ask for something that cost that much, but that hasn't happened yet. We do occasionally get applications that tell us that the Institution is willing to put in whatever the difference is between $300,000 and $400,000 or $300,000 and $500,000.

Senator WEICKER. So that if we were to add moneys into your particular Institute, where should we add them to get benefit in the area of the subject matter we're discussing here?

Dr. PICKETT. This Shared Instrumentation Grant Program is under the biomedical research support line. It is a separate, distinct part of that program.

## BIOMEDICAL RESEARCH SUPPORT GRANT PROGRAM

Senator WEICKER. Last year the administration sought to reduce the Biomedical Research Support Grant Program by $21 million. Congress rejected that proposal. How much did you finally allot to the program in fiscal 1984 and was there any lateness in getting money out because of your effort to cut funds?

Dr. PICKETT. We allotted $47,417,000 for the BRS Grant Program in fiscal year 1984. We have been able to make the awards on time. All the calculations have been done, the printouts are ready, and the awards have been prepared and mailed.

Senator WEICKER. What will be the effect of level funding for the Support Grant Program in fiscal 1985 that you propose?

Dr. PICKETT. Well, we will actually make a few more awards, because a few more institutions will become eligible under the $200,000 threshold. The range of award size has not been changing much. The minimum award may become slightly lower than it is now. The trend is going down. It was $9,120 in fiscal 1983. The actual minimum award in fiscal 1984 is $8,465. The average size award in 1984 is $86,313. The maximum award in 1984 is about $291,000, so the effect of level funding will hit the lower reaches of eligibility most prominently.

## INSTRUMENTATION NEEDS

Senator WEICKER. If you had to ask for a figure that could be meaningful in terms of additional moneys for instrumentation, what would you ask for?

Dr. PICKETT. Our calculations of the so-called shortfall estimate would call for $13.4 million, which would enable us to reach all of the expected approvals with fundable priority scores. That is, we expect that we will have 150 to 155 approvals that would be worthy of support, if we follow the priority cutoff that we have been following up to this point. With that great increase in numbers, it would take $13.4 million more to fund all of those.

Senator WEICKER. Do you think we can handle that, Tony?

Mr. ITTEILAG. Well, Mr. Chairman——

Senator WEICKER. I'll change my tactics with this guy. He's one of the smartest men I've ever seen with a budget, and I'm just going to get him to work this thing on my side. [Laughter.]

He knows where to find it.

Mr. ITTEILAG. Mr. Chairman, there are always more good things to do than there is money available to do it. I don't think there is any dispute over that.

Senator WEICKER. I've got a few more weeks to work on him. [Laughter.]

Brainwashing hasn't been completely successful, but we'll get to that.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

All right. Thank you very much.

We'll have further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### FORMULATION OF DRR BUDGET REQUEST

Question: To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: We were consulted throughout the formulation of the 1985 budget request, and were initially allowed to develop the budget according to our own program plans and priorities. At each level of the review process -- NIH, PHS, DHHS, and OMB -- the budget request was adjusted in accordance with priorities and policies held by that level. We were given some latitude, within our assigned levels and within the overall Administration priorities, to make our budget request as responsive as possible to the needs of the biomedical research community.

### IMPACT OF BUDGET REQUEST

Question: What is the impact of the budget request on your Division and what will it do to the scientific momentum you are trying to maintain?

Answer: The 1985 budget request for the Division of Research Resources will allow us to maintain the Biomedical Research Support Grant Program at the same dollar level as in 1984, and maintain the same number of other grants and contracts in 1985 as in 1984. Each of these grants will be negotiated downward according to principles of prudent management, and on a case-by-case basis, by amounts ranging from 3.9 percent to 7.0 percent. The negotiation process will enable the Division to maintain support to its existing resources and centers at a program level somewhat below 1984. This option was chosen based on the ongoing nature of resource grants and the long-term investments already made. It would be unwise to phase out good quality, existing resources, in view of the high start up costs of a subsequent reinstatement of such resources. This strategy should have the least impact on the scientific momentum of the users of our resources and centers.

The 1985 budget request includes funds for a single new initiative. We must provide now for the expansion and updating of the PROPHET computer network. The PROPHET network has been successful as a pioneering effort in delivery of major computing power to biomedical research scientists; it is a unique resource for about 800 investigators. The 1985 request for PROPHET will enable a start on the needed update, and will increase access to the system for a wider group of scientists.

### MAINTAINING THE CENTERS PROGRAM

Question: With funding for research centers held roughly at current levels, how do you expect to maintain the same centers program in FY 85 that you had in FY 84?

Answer: The 1985 budget request for the Division includes a 1.0 percent dollar increase over 1984 levels for each of our centers programs -- general clinical research centers, biotechnology resource centers, primate research centers, and laboratory animal sciences centers. We intend to maintain support to all of our currently existing centers, but at a reduced program level. With hospital care costs increasing at a rate of between 6 percent and 8 percent annually, we anticipate that we will need to negotiate each of our general clinical research center awards downward between 5 percent and 7 percent from projected costs, the percentage to be determined after careful negotiations on a grant-by-grant basis. With costs projected to rise an average of 4.9 percent in our other centers programs, we plan careful negotiation of all our other center awards, on an individual grant-by-grant basis, by an average of 3.9 percent from projected costs.

We arrived at this negotiation plan after careful consideration of all the options. On balance, in view of the ongoing nature of resource center grants and the long-term investment already made, it seemed unwise to phase out good quality, existing resources.

## MAINTAINING 1984 LEVEL OF EFFORT

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your institute at the same level of effort as in fiscal 1984?

Answer: In order for the Division of Research Resources to maintain the same level of effort as in 1984, we would need an additional $11.3 million over the 1985 request. This would enable us to meet our commitments fully, and maintain support to all currently existing grants and contracts, without downward negotiation of direct costs, and would also enable us to proceed with the proposed expansion and updating of the PROPHET computer network which is already included in the 1985 request.

## PROPOSED FTE REDUCTIONS

Question: The budget proposes a staff cut of 588 for all of NIH, what is your share of this proposed reduction -- and where will you take it?

Answer: Our share of the 588 full-time equivalent (FTE) reduction is 4 FTE's. We will take this reduction in our Research Management and Support activity.

Question: With what effect on research?

Answer: We will make every attempt to implement the reduction in a way that will minimize the impact on our programs and on the effective management of the Division. This proposed reduction will not have a direct effect on research *per se*, as we do not conduct any intramural research. We will take the reduction of 4 FTE's in the area of Research Management and Support, which provides for the overall management, administration, direction, coordination, planning and evaluation of the Division and its' programs.

INSTRUMENTATION

Question: You make a good point in your budget justifications that research institutions are having difficulty finding the money to replace worn out or obsolete equipment with the more sophisticated instruments they now need. What are you doing about this problem and how much will you spend on your program to make new instruments available to researchers?

Answer: The Division supports the acquisition and development of instruments required for a broad spectrum of biomedical research activities through the Shared Instrumentation Grant (SIG) Program, the Biotechnology Resources Program, and the shared instrumentation grant program in the Minority Biomedical Research Support Program.

The objective of the Biomedical Research Support Shared Instrumentation Grant (SIG) Program is to make available to institutions that have a high concentration of NIH research awards research instrumentation which can be justified only on a shared-use basis, and for which meritorious research projects are described. This program provides commercially available instruments for routine research use costing in the range of $100,000 to $300,000. Examples of instruments purchased include electron microscopes, cell sorters, mass spectrometers, nuclear magnetic resonance spectrometers, X-ray diffractometers, image analysis facilities and computer graphic systems. The SIG Program, begun in 1982, has grown from a level of $3.7 million in 1982 to $19.770 million in 1984, and requested in 1985. The Division made 23 SIG awards in 1982, 91 in 1983, and expects to make 114 in 1984. For FY 1985, 224 applications have been received to date. It is estimated that we will be able to fund between 85 and 110 of these applications.

The DRR Biotechnology Resources Program awards grants to develop advanced, sophisticated instruments and technologies to be used on a regional or national basis. This Program provides high technology instruments such as large-scale and minicomputer systems, mass spectrometers, electron microscopes, electron microprobes, and other equipment embodying advanced technological developments at the forefront of biomedical research. The Program has grown significantly in recent years. From 1982 to 1984, the Program's budget increased by $12.3 million, from $20.2 million to $32.5 million. The 1985 President's request level of $34.4 million reflects an increase for the Biotechnology Program of 6.1 percent over the 1984 level.

Shared instrumentation grants are provided in the Minority Biomedical Research Support (MBRS) Program in order to address problems of instrumentation obsolescence and shortage at minority institutions. This new program began in 1983 with 23 awards at a cost of $1.27 million. Fewer applications were submitted in 1984, and we anticipate approximately 18 awards at a cost of $1.0 million. In 1985 $1.0 million will again be available for continued support of instrumentation at minority institutions. The types of instruments requested through this program include spectrophotometers, spectrometers, high pressure liquid chromatographs, scintillation counters, centrifuges, microscopes, and computer systems.

Question: In his November speech to the Association of American Medical Colleges, Dr. Wyngaarden talked about the need for $20 million a year for five years to replace or purchase sophisticated research instruments. How will your budget contribute to this need?

Answer: Through our Biomedical Research Support Program we support the Shared Instrumentation Grant program; its objective is to make available to institutions with a high concentration of NIH research awards research instrumention which can be justified only on a shared-use basis and for which meritorious research projects are described. This program provides commercially available instruments for routine research use costing in the range of $100,000 to $300,000. Examples of instruments purchased include electron microscopes, cell sorters, mass spectrometers, nuclear magnetic resonance spectrometers, X-ray diffractometers, image analysis facilities and computer graphic systems.

Our 1985 budget request for the Shared Instrumentation Grant Program is $19,770,000. We anticipate that this sum will fund between 85 and 110 Shared Instrumentation Grants in 1985, and continue our efforts to ease the problems of instrumentation obsolescence and shortages at institutions conducting biomedical research.

## BIOMEDICAL RESEARCH SUPPORT GRANTS

Question: Last year the Administration sought to reduce the Biomedical Research Support Grant program by $21 million. Congress rejected this proposal. How much did you finally allot to the Program in fiscal 1984 and was there any lateness in getting the money out because of your efforts to cut the funds?

Answer: The Biomedical Research Support Program received $68,187,000 in the 1984 appropriation. This consisted of $47,417,000 for the Biomedical Research Support Grants, $19,770,000 for the Shared Instrumentation Grants, and $1,000,000 for the Minority High School Student Research Apprenticeships. There was no delay in awarding these funds because of the Administration's proposed reductions. All of the Biomedical Research Support Grants were made, as planned, on April 1, 1984. All of the Minority High School Student Research Apprenticeship awards were made, as planned, on March 1, 1984. The Shared Instrumentation grants have also been made in a timely manner.

## BRSG ELIGIBILITY THRESHOLD

Question: Congress also rejected your proposal to raise the threshold for eligibility to receive the Support Grants, a step which could have prevented many nursing, pharmacy and dentistry schools from participating in the program. We assume there has been no change in the current threshold.

Answer: That is correct; there has been no change in the current threshold. It had been proposed to raise the eligibility threshold from $200,000 to $350,000 in 1983, and to $500,000 in 1984. When Congress rejected this proposal, we maintained the eligibility threshold at $200,000, and awards were made accordingly in both 1983 and 1984. At the present time, the eligibility threshold stands at $200,000, and we have no plans to raise it in the foreseeable future.

## 1985 BUDGET LEVEL FOR BRSG

Question: What will be the effect of level-funding the Support Grants program in fiscal 1985 as you propose?

Answer: There will be minor impact on the Biomedical Research Support Grants (BRSG) Program as a result of the 1985 budget request. In 1985 the Program will have available $47,417,000, the same level as in 1984. Based on historical trends, we anticipate between 20 and 30 new institutions will become eligible for BRS grants as a result of their receiving at least $200,000 of Public Health Service grant support. These two factors -- increase in the number of eligible institutions, and the increasing cost of conducting biomedical research at all institutions, will have the effect of reducing the size of the average BRSG award from $86,313 in 1984 to approximately $82,000 in 1985.

## MINORITY HIGH SCHOOL PROGRAM

Question: I have heard some positive things about your summer program for minority high school students. Apparently the program has been a success in encouraging bright high school students to pursue careers in health and research. I note that you received $1 million for the program in fiscal 1984 and are asking the same amount for the new fiscal year. To what extent will your proposal result in cutting back the level of activity or support under the program?

Answer: There will be no adverse effects on the Minority High School Student Research Apprenticeship Program as a result of maintaining the Program at $1.0 million in 1985. The purpose of the apprenticeship program is to provide meaningful experience in various aspects of health-related research in the expectation that some of the apprentices will decide to pursue careers in research related to health. This level of funding will enable the Division to provide support to 666 students in 1985, the same number as in 1984 and 1983. Support is provided at a level of $1,500 for each apprentice position allocated. Salaries are paid to the students at the prevailing scale for comparable work, and each apprentice must be offered a minimum of eight weeks full-time experience. Because of these program guidelines, the $1,500 per apprentice position has been sufficient to cover the costs of the program. Therefore, the $1.0 million requested in the 1985 budget will not result in any cut backs to the level of activity or support provided under the program.

## MINORITY BIOMEDICAL RESEARCH SUPPORT PROGRAM

Question: You also are requesting level funding at $21.8 million for the Minority Biomedical Research Support program which is university oriented. Here again, doesn't this mean that you will have to cut back on support for the 74 institutions participating in the program?

Answer: With the $21,879,000 included in our request for 1985, and the additional funds provided by the other NIH Institutes and the National Institute of Mental Health, the total amount available for the program in 1985 is $32,043,000. This level of funding will enable us to continue support to the same number of awards as last year, and also provide $1.0 million, for the second consecutive year, for shared instrumentation awards at Minority Biomedical Research Support institutions. It will, however, be necessary to negotiate carefully, and on a grant-by-grant basis, the direct costs of these 74 awards. We anticipate reductions on the average of approximately 4.9 percent from projected full costs.

## John E. Fogarty International Center for Advanced Study in the Health Sciences

### STATEMENT OF DR. CRAIG K. WALLACE, DIRECTOR

**ACCOMPANIED BY:**

- **DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **DR. CORALIE FARLEE, ASSISTANT DIRECTOR FOR PROGRAM OPERATIONS**
- **ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator Weicker. Next we shall hear from the Fogarty International Center which administers exchanges of biomedical scientists and scientific information between the United States and foreign countries. Fogarty also has responsibility for channeling the annual appropriation to the Gorgas Memorial Institute and the Gorgas Laboratory, which conducts research into tropical diseases through its facilities in Panama. Gorgas became controversial last year when the administration tried to cut off its funding. Following studies by GAO and the Office of Technology Assessment, our subcommittee recommended further funding of Gorgas and Congress agreed.

The budget request for Fogarty is $11.4 million, an increase of about $90,000 over the fiscal 1984 appropriated level. Included in that request is $1.9 million for the Gorgas Laboratory.

Dr. Craig Wallace, the Director of Fogarty, is here to testify on behalf of the budget request.

Welcome, and you may proceed.

[The statement follows:]

## STATEMENT OF DR. CRAIG K. WALLACE

It is a pleasure to appear before you on behalf of the Fogarty International Center to report our progress and plans. I was privileged to become the Director during January of this year, previously having had the opportunity to experience firsthand the significance of international biomedical research, both as a research investigator and administrator. Indeed, over half of my professional experience has been spent abroad and I have closely observed the continuing and significant new activities that fulfill the original purposes of the Fogarty International Center as envisioned when established in 1968.

As a part of the National Institutes of Health, the Center shares in the fundamental mission of advancing knowledge about disease processes and disease prevention to improve the health of the American people. At the same time, this mission serves health on a global scale. Our Center has the particular responsibility among the NIH components to stimulate and enhance biomedical cooperation within the international community to achieve these ends.

Some basic concepts integrate and mutually reinforce all activities of the Fogarty International Center:

o The linkages that we develop and strengthen between the American biomedical scientific community and those of other countries make it possible to draw upon ideas, resources, and particular environmental conditions existing beyond our borders, now and in the future. Thus, NIH maintains its leadership role through interaction with biomedical scientists worldwide;
o The studies selected and undertaken in the biomedical sciences are those only, or best, addressed from an international perspective.

In specific fulfillment of our mission, we continue to emphasize special studies of an international nature. Our International Studies Program has focused recently on infectious diseases, specifically, the control and, hopefully, eradication of measles, poliomyelitis, yaws, and rubella. Our international symposium on poliomyelitis, held in 1983, concluded that while the United States has substantially eliminated clinical poliomyelitis, the threat to us remains as long as the disease is still a major health problem in many other countries. This conference focused attention and crystallized the need to apply current knowledge and experience for the benefit of the millions of people who remain at risk.

During April, the global impact of yaws, occurring primarily in tropical regions, will be assessed and control strategies discussed. Prior to 1950, 160 million individuals in the tropics were infected with yaws, a non-venereal spirochetal infection that can vary from skin lesions to massive destruction of tissue, joints, and bone as well as facial disfiguration. Mass campaigns sponsored by the WHO and UNICEF during the 1950s and 1960s resulted in a drastic reduction in this disease worldwide; however, lack of surveillance and continued control measures have resulted in a resurgence of yaws during the past decade. As with smallpox, the basis for eradication of yaws is within our grasp through present state-of-the-art techniques.

Rubella--German or 3-day measles--is usually a mild illness, but in a pregnant woman the infection can be devastating to the fetus, particularly in the first trimester of pregnancy. Major resulting congenital abnormalities all too often include cardiovascular lesions, deafness, cataracts, as well as growth and mental retardation. In the United States, while there has been substantial progress in control, rubella has not been eliminated. Its incidence in Africa, Asia, and South America, however, remains high, with major epidemics occurring every 7-10 years. Here, again, the opportunity exists to not only eliminate rubella with its risk of congenital rubella in the United States, but to globally promulgate this knowledge and capability. We are presently addressing this specific aspect in another international symposium.

A key element in the Fogarty International Center is the Scholars-in-Residence Program. World renowned biomedical and behavioral scientists are invited to the NIH for wide ranging, dynamic interaction with scientists at NIH. The environment which we are able to create provides an opportunity for the visiting scientist to focus, without distractions, on major health and disease problems. Illustrative of these scholars' activities was a recent workshop that explored the concept of bacterial cloning as it relates to risk of disease and opportunities for vaccine development. The principles discussed at this conference are potentially important in the development of future vaccines and prevention strategies. A further illustrative and significant scholar-initiated conference will consider during April "Immunity to Schistosomiasis." This parasitic disease affects an estimated 200 million individuals and is potentially incapacitating to Americans in their ever increasing global commitments. Although rarely fatal, schistosomiasis is extremely debilitating in both its initial appearance and chronic state.

A fundamental concept underlying all Fogarty Center activities is the establishment of channels of communication--linkages--between American scientists and those of other countries. Our international fellowships and exchange programs address this objective directly. These programs have brought together scientists of the United States and those of other countries to conduct important research studies in a wide range of biomedical disciplines. Recent assessments of this program have shown that these scientists generally become leaders in their fields, forming a creative network for future transmission of new ideas and research often with an underlying commitment to the United States.

In pursuit of opportunities for United States scientists to gain international experience, we have fostered exchange and fellowship support from other sources, indeed, many from abroad. Specifically, in 1982, we began to serve as a channel for fellowships offered by the Alexander von Humboldt Foundation in West Germany, and in 1983, we began to administer the Irish Medical Research Council Fellowships in addition to programs already established with France, Sweden, and Switzerland. New programs with Italy, Israel, and Finland are under development.

The Center is the focal point for the development and oversight of NIH participation in both formal and informal cooperative agreements and programs with other countries. Presently 49 agreements with 29 countries form much of the framework for cooperative international research projects of all NIH components. Studies of disease prevention are prominent among these activities. As examples, the United States-China agreement provides for exchange of scientists in a variety of fields including cancer, cardiovascular disease, genetics, and reproductive physiology. Research in blindness prevention and immunological studies will be developed as collaborative projects under a new program with India. The recent United States-Mexico Commission on Science and Technology determined five areas of common interest in biomedical science including acute respiratory infections and diarrheal diseases.

This has been a brief overview of selected research-oriented activities of the Fogarty International Center. To support these activities, as well as our necessary and extensive service functions to the international community which form an essential ingredient of the NIH mission, we are requesting $9,527,000 for FY 1985. The Fogarty International Center serves as administrative conduit for the $1,899,000 core funding of the Gorgas Memorial Laboratory in Panama. The total appropriation requested for these activities for FY 1985 is $11,426,000, an increase of $19,000 over the comparable 1984 level. Mr. Chairman, I would be happy to answer any questions.

## BIOGRAPHY OF DR. CRAIG K. WALLACE

December 4, 1928. Woodbury, N.J. Married, three children.

Education. A.B. (cum laude), Princeton University, 1950. M.D., New York Medical College, 1955.

Professional History. 1955-1960, Intern, Medical Resident, and Chief Resident, Jefferson Medical College Hospital, Philadelphia, Pa. 1960-1963, Clinical Investigator, Naval Medical Research Unit (NAMRU) No. 2, Taipei, Taiwan. 1964-1969, Assistant Professor of Medicine, The Johns Hopkins University School of Medicine. 1964-1970, Assistant Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1964-1966, Resident Coordinator and Head, Medical Program, The Johns Hopkins University Center for Medical Research and Training (CMRT), Calcutta, India. 1966-1969, Assistant Physician, The Johns Hopkins Hospital. 1967-1972, Associate Director, The Johns Hopkins University CMRT. 1969-1972, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1969-1972, Physician, The Johns Hopkins Hospital. 1971-1972, Associate Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1972-1974, Head, Research Detachment, NAMRU-3, Addis Ababa, Ethiopia. 1974-1976, Commanding Officer, NAMRU-5, Addis Ababa, Ethiopia. 1976-1978, Program Manager, Infectious Diseases Research, Naval Medical Research and Development Command, Bethesda, Md. 1978-1981, Chief of Internal Medicine, Naval Regional Medical Center, Camp Pendleton, Calif. 1981-1982, Director of Clinical Services, Naval Regional Medical Center, Jacksonville, Fla. 1982-1984, Commanding Officer, NAMRU-3, Cairo, Egypt.

Professional Organizations. Fellow of the American College of Physicians; Fellow of Infectious Diseases Society of America; Fellow of the Royal Society of Medicine; Fellow of the Royal Society of Tropical Medicine; American Association for World Health; American Medical Association; American Society for Microbiology; American

Society of Tropical Medicine and Hygiene; Association of Military Surgeons of the United States; The National Foundation for Infectious Diseases.

Honors, Awards. Armed Forces Reserve Medal, 1975. Meritorious Service Medal, with Gold Star in lieu of the Second Award, 1976, 1984. Navy Commendation Medal, 1982.

### OVERVIEW OF THE FOGARTY INTERNATIONAL CENTER

Dr. WALLACE. I think I can probably best characterize the Fogarty International Center's function by quoting the late Congressman Fogarty, who said "I am personally of the conviction that through leadership in international medical research and research training activities, the United States can contribute in a particularly meaningful and effective way to the solution of health problems, specifically, and the cause of peace, generally."

And this is what the Fogarty International Center is all about. We have heard a lot in the last 2 days about figures and numbers, and I'd like to share three with you that I think are very meaningful, as far as the Fogarty International Center is concerned. In fiscal year 1983, 283,813,539 Americans and foreigners entered the United States from abroad. Also in fiscal year 1983, 1.8 million American citizens were living abroad, and this excludes 300,000 to 400,000 American military and their families. And in fiscal year 1984, it is estimated that 25 million Americans will leave the United States by air. These travelers, as well as residents of the United States, will benefit from advances gained from international collaborative research represent our constituency.

### INTERNATIONAL COORDINATION AND LIAISON PROGRAM

Now how does the Fogarty International Center address problems of international concern? We actually have four programs. First, the International Coordination and Liaison Program coordinates all activities and functions of the National Institutes of Health concerned with the health sciences at the international level. We at the National Institutes of Health participate in 49 bilateral agreements with some 29 countries, which the Fogarty International Center helps to negotiate, administer, and coordinate.

### INTERNATIONAL RESEARCH AND AWARDS PROGRAM

Second, the International Research and Awards Program administers research fellowship awards for postdoctoral fellows and established scientists both in the United States and abroad. We also support under this program, senior scientist exchanges between the United States and other foreign countries.

## FOREIGN SCIENTISTS ASSISTANCE PROGRAM

The Foreign Scientists Assistance Program provides administrative support and serves as a focal point for foreign scientists who come to the National Institutes of Health for research collaboration.

## ADVANCED STUDIES PROGRAM

Finally, the Advanced Studies Program has two elements. One area is the Scholars-in-Residence Program which provides a facility for the assembly of scientists, world leaders in biomedical fields, for discussion, study and research, relating to the development of science internationally. We characterize this program as a think tank. We have at the present time 10 internationally known figures who facilitate and stimulate activities between the Fogarty International Center, the categorical institutes and, indeed, among institutions worldwide. One of these activities has led to a conference which the Fogarty International Center will support, that will address the matter of immunity against schistosomiasis. This disease is probably one of the world's major causes of suffering.

The other component of our Advanced Studies Program is the International Issues Study Program which furthers international cooperation and collaboration in the life sciences through various research programs, conferences, and seminars. We attempt to address problems of international concern which will concentrate the expertise of the National Institutes of Health on the needs of the world as well as the United States. We are working in liaison with the World Health Organization in trying to control or eradicate certain diseases. Specifically, we have addressed studies on measles, polio, and recently yaws and congenital rubella. We have underway a study on the appropriate use of antibiotics.

We also intend to follow up on progress in control and eradication of diseases discussed earlier.

I will be happy to answer any questions.

## GORGAS MEMORIAL INSTITUTE

Senator WEICKER. Last year, the administration tried to cut off funding for the Gorgas Memorial Laboratory in Panama. Congress rejected that. However, the studies by GAO and the Office of Technology Assessment did suggest that Gorgas strengthen its financial base, do a better job of scientific review of projects, do long-range planning and do more collaborative work with American universities.

To what extent is Gorgas responding to the recommendations for improvement?

Dr. WALLACE. I am delighted to report that Gorgas is responding in a very positive fashion. They have addressed a reorganization of their structure, and have had a RIF. To quote the current laboratory director, "It's going to be a leaner, meaner, more aggressive laboratory." They have also instituted a peer review system of their scientific articles. The

Deputy Director of the Fogarty International Center has just been in Panama to visit the Gorgas Memorial Laboratory and to plan future technical consultations which can address both ongoing and future scientific activities.

I think Gorgas has been extremely responsive to the concerns of Congress.

Senator WEICKER. Have you been down there to the Gorgas Laboratory?

Dr. WALLACE. No; I have not.

Senator WEICKER. Have you or Dr. Wyngaarden been down there?

Dr. WYNGAARDEN. No; I have not.

Dr. WALLACE. My Deputy Director has just returned, Senator. I was unable to go because of the present hearing.

[The information follows:]

## LETTERS FROM LEON JACOBS, PH.D., PRESIDENT, GORGAS MEMORIAL INSTITUTE OF TROPICAL AND PREVENTIVE MEDICINE INC.

15 March 1984

Hon. Lowell P. Weicker, Jr., Chairman
Labor - HHS - Education
Appropriations Subcommittee
186 Senate Dirksen Office Building
Washington, D.C. 20510

Dear Senator Weicker:

This responds to the additional OTA comments on the Gorgas Memorial Institute report submitted to the Senate SubCommittee on Appropriations for Labor, HHS and Education. The OTA comments were contained in a memorandum of 19 February to the Subcommittee. A copy of this memorandum was received by GMI while I was visiting the Gorgas Memorial Laboratory in Panama. When I returned, I was involved in the annual meeting and other activities; hence the delay in this response.

First, a general statement: The OTA comments indicate dissatisfaction with the length of the Gorgas response and with the general and vague nature of the discussions of actions being taken, or planned, on the basis of OTA and GAO recommendations. I personally must take responsibility for these perceived deficiencies. My conception was that the Senate Subcommittee and its staff would appreciate a brief and succinct report, without the elaboration of details. OTA does mention that it may be too early to expect more detail, but also states that it has been more than six months since Gorgas knew that changes should be considered. My answer here is that we have already made some changes, as stated in the original Gorgas response, and that others have been initiated, but will take considerable time to be developed in full. It is now necessary to go into some detail.

The suggestion was made that GML scientists and management be more aggressive in publishing the results of their research. This is something with which Gorgas management has been concerned for several years. In early 1981 I completed a consolidation of the annual reports of GML for the years 1979 and 1980, for the then President of GMI, Dr. Jack W. Millar. I made a recommendation to Dr. Millar, at that time, that annual reports should contain summary statements of scientific studies, but that the scientific data and discusstions should be published separately, preferably in reviewed journals. This recommendation was transmitted to the then Director of GML, who protested that some data, especially negative results, were generally not accepted by scientific journals but were nevertheless valuable. My response, in a letter signed by Dr. Millar in April 1981, was that there is a repository for such data in the National Technical Information Service (NTIS) and that scientific journals will publish research notes recording the deposition of such data in NTIS. The reason for these suggestions was precisely what OTA recognized as a deficiency, i.e. lack of aggressive publication by GML scientists. Current policy of GMI/GML is to require publication in scientific journals that conduct peer reviews of submitted articles. Prior to submission to the journal, GMI provides for what we consider an "internal" review, that is, examination by two members of our Advisory Scientific Board (ASB).

The essential points of this new policy and practice are:

1) To assure that GML findings and accomplishments are made available to the scientific community. (This was not a deficiency on the part of all GML scientists in the past, but did affect some of them);

2) To subject GML scientific projects and capabilities to review by ASB members. As mentioned elsewhere, the ASB members involved in such reviews become acquainted more intimately with the programs of GML. Although this is a slow precess, it adds to the effects of other review mechanisms.

I must state here that the recent uncertainties of funding of GMI - not only in FY 1983 but in earlier years - detracted significantly from the productivity of GML scientists. This factor has been recognized in the OTA report but it requires emphasis. When individuals are worried about the stability of their employment, and considering other possibilities, they cannot concentrate on their research. As recognized in the OTA report, it is the degree of uncertainty that is important. The degree is enhanced when one is situated overseas, because it is more difficult to look for a job.

The OTA memo states: "Even by itself, the use of the ASB to review manuscripts is an excellent idea, but it cannot be simply a 'paper policy'. GMI/GML must implement it actively, and the ASB members must take the responsibility seriously. It should be an explicit requirement of membership on the ASB that its members take the time to give manuscripts a thorough critique." A "paper policy," if I understand it correctly, is what we used to call "eyewash" in the Army, i.e. something put on only for show. I assure you that our policy is not for show. I can also state with certainty that although we have never made it an explicit requirement that an individual nominated to the ASB indicate his/her willingness to review manuscripts, I have had only good responses from members asked to do reviews; they are pleased to participate.

Regarding assuring the quality of research at Gorgas, I must state that the management of GMI and GML are acutely aware of this issue. Statements about the lack of an effective peer review process for allocating support to research projects funded by core money have been made so repeatedly that we would have to be extremely insensitive not to heed them. We have already mentioned our meeting with ASB members at San Antonio in December 1983. This was a first step in involving ASB in program planning and project review. We will do more when we have attained enough financial stability to allow us to fund site visits of ASB members to GML and to provide for planning sessions of all or parts of the Advisory Scientific Board. We cannot spend more than a small percentage of our funding on peer review, and we therefore will have to rely to a great extent on written communications. By such communication, we can obtain critiques of proposed programs and projects and also suggestions for projects. ASB members at San Antonio suggested that we should take advantage of trips that ASB members take to Latin America for other purposes, by having them stop at Panama on their way. Whenever this is feasible, we will do so, because the per diem expenses of such short visits would be relatively small.

The OTA memo states: "We strongly urged consideration of increased use of collaborative arrangements with universities, other countries, and international organizations. We find no information on whether Gorgas plans to pursue such arrangements."

I am remiss in not making a statement about these comments in the response to the Senate report. However, in the OTA Technical Memorandum of August 1983, page 21, there are two paragraphs describing the number of students and visitors who came to GML within the past year and also the academic and governmental institutions with which GML has working relations. GML has not completed its move into its buildings in Panama City because renovations have proceeded slowly. Until all of the staff are relocated and the laboratories are working smoothly, it is difficult to expand our collaborative activities. We certainly intend to do so, but these things cannot be started just a few months after a period of considerable unrest. Other institutions cannot be expected to enter into arrangements with an organization that is in the kind of precarious financial status that we recently experienced. Moreover, we do have some arrangements with WHO and PAHO, listed in table 7 of the Technical Memorandum. The development of collaborative arrangements will be easier when we acquire some additional space in Panama City, which is likely after we relinquish Building 265 in Ancon. (The Ministry of Health of Panama will take over Building 265 and will make available to us, without charge, some office space in a building close to ours). It will also be easier for GML to accommodate Visiting

Scientists and Fellows. Certainly, Gorgas has put thought and energy into visiting programs, but we have been so hampered by meager funding and space problems that most of this effort has been to no avail.

Regarding the changes in by-laws mentioned in the Gorgas response, as soon as we can provide a complete set of by-laws incorporating the modifications we will do so. The most important are listed below:

1. The number of members on the Advisory Scientific Board has been increased to 36, to provide GMI/GML with a wide variety of expertise.

2. A new category of Director, Director Emeritus, has been established, to provide special status to individuals whose activities are now more limited but whose advice and assistance are sometimes sought. This enables us to create more vacancies on the Board of Directors. We hope to fill these vacancies with individuals from the business and banking communities.

3. The Chairman of the Board is now an officer separate from the President. Until a President is appointed, however, the Chairman serves in that capacity. The President will be a full-time paid Chief Executive Officer. Gorgas is acutely aware of the costs of a paid executive and it will be some time before such an individual will be recruited. In the long run, it is hoped that the President can serve in the fund-raising activities of GMI, to compensate for his own salary and the additional expenses of an enlarged office. The expansion of the office and the fund-raising enterprise will have to be coordinated at the appropriate time. We are feeling our way into these new areas, and hope to engage business expertise on our Board of Directors before we go too far.

Fund-raising activities would not include helping individual GML scientists apply for grants and contracts.

It is not anticipated that the Panamanian fund-raising effort will be very productive. However, we agree with the OTA memo as to what the funds could be used for.

Regarding "strategic plans to move into innovative areas of biomedical research", the examples given in the OTA Technical Memorandum (p. 57), monoclonal antibodies and biotechnology approaches to vaccine-related research and development, I am sure that GML scientists will be receptive to such new programs provided the resources are available. The types of technology given as examples are highly demanding of personnel and resources, and it may be possible to establish collaborative arrangements when complicated projects, requiring a considerable range of expertise, are undertaken. The example given in the OTA memo (footnote, p. 57) of the International Laboratory for Research on Animal Diseases, Kenya, as a field unit where important work at the forefront of science has been done, is a good one. ILRAD has indeed had some significant contributions, using the techniques of molecular biology, to the understanding of antigenic variation in African trypanosomes. I can point out that isozyme analysis of variants of Leishmania has been used in GML for some years. While this technique is not so new as those used in molecular biology, its use at GML is indicative of the ability of our scientists to apply new methodology as it becomes available. I am not sure that I understand how the centers supported by the Rockefeller Foundation's Great Neglected Diseases Program represent "other examples". The OTA memo suggests (p. 2, last paragraph) that Gorgas could perhaps, be requested "to provide information on the directions in which its research program is moving" "into developing areas of science". I can answer only that we have just offered employment to a young Panamanian scientist who has just completed her doctoral training in immunology at the University of Notre Dame, South Bend, Indiana. We anticipate that she will be able to initiate some new studies on a variety of infectious agents. As we achieve more stability, we will recruit additional expertise.

**I believe I have now covered all the points raised by the OTA memo. I am perplexed by the amount of detail requested by OTA. I hope this response is adequate.**

**Sincerely,**

**Leon Jacobs, Ph.D.**
**President**

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27 January 1984

Hon. Lowell P. Weicker, Jr., Chairman
Labor - HHS - Education
Appropriations Subcommittee
186 Senate Dirksen Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

I am pleased to transmit to you, herewith, the report of the Gorgas Memorial Institute prepared in response to the report of the Senate Committee on appropriations for fiscal year 1984, no. 98-247. This report outlines actions taken and planned by GMI as suggested by the critique on GMI/GML provided by the OTA and GAO reports to your subcommittee last August and September.

Here, again, I wish to convey my personal appreciation and the gratitude of GMI/GML as a whole, for the careful consideration you and your subcommittee and staff have given to the support of our efforts in tropical disease research and control.

Sincerely,

Leon Jacobs, Ph.D.
President

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## REPORT NO. 98-247, GORGAS MEMORIAL INSTITUTE

In the course of resolving the question of funding the Gorgas Memorial Institute (GMI) and Laboratory (GML) thru the administrative channel of the fiscal year 1984 appropriations for the Fogarty International Center of the National Institutes of Health, Congress directed reviews of GMI/GML by the Office of Technology Assessment and the General Accounting Office. The recommendations of these congressional agencies were used in the formulation of the report of the Senate Committee on Appropriations for the Departments of Labor, HHS, and Education.

The comments and recommendations of the GAO and OTA included the following:

"Each year the United States sends a message to Panama and the region by funding GML and supporting activities related to the health of U.S. and Panamanian citizens alike." (OTA)

"The overall scientific quality of GML is high."...."the research conducted....at GML is relevant to the various parties at interest." (OTA)

"Gorgas is not ideal; improvements could certainly be made." (OTA)

"Minimal Latin involvement in the decision making process." (GAO)

"Little has been done to expand the Institute's financial base of support." (GAO)

"The Institute's Advisory Scientific Board is not being fully utilized." (OTA & GAO)

"Long-range planning of Laboratory activities is lacking." (GAO)

"Gorgas itself could improve....by more involvement by the Advisory Scientific Board in the planning, execution and review of Laboratory activities." (GAO)

"....by actively seeking out association and collaboration with.... universities....and international organizations." (OTA)

"....by making strategic plans to move into the developing areas of modern science." (OTA)

"....by making an effort to run vigorous visiting and fellowship programs." (OTA, citing monoclonal antibodies, immunological diagnostics, and cancer.)

The Senate report (page 83) directs Gorgas "to review the studies and to provide it with a report prior to the fiscal 1985 hearings as to how it plans to implement the recommendations made by GAO and OTA."

We regard the two reports as exceptionally constructive and providing guidance for the development of GMI and GML.

The following actions have been taken by GMI/GML in response to the OTA and GAO reports:

1) A policy has been instituted to utilize the Advisory Scientific Board in the review of all scientific papers produced by the GML. The papers are sent to at least two members of the Advisory Scientific Board prior to submittal to a journal for publication. The reviewers are, of course, selected on the basis of their own special fields of interest. They are asked to provide their judgment on whether the data are worthy of publication or should be deposited in the National Technical Data Center. They are also expected to give the usual type of critique of papers they consider publishable, i. e., the methods of investigation and of data presentation and analysis and the validity of the conclusions reached, etc. These comments are returned to GML to assist the author in making modifications, if necessary, before sending the paper to a journal. The comments also serve to aid the Director, GML, in making assessments of the strengths and weaknesses of his scientific staff.

This practice also will provide members of the Advisory Scientific Board with specific material on which to judge the quality of the GML program and staff. It will be increasingly valuable when the ASB members have examined enough papers to provide them with an adequate sampling of the research product. It is corollary to the next action.

2) A meeting of members of the Advisory Scientific Board was held at San Antonio, Texas, on 7 December 1983, at the time of the joint meetings of the American Society of Tropical Medicine and Hygiene and the American Society of Parasitologists. This site and time were chosen to take advantage of the presence of a number of Board members at the professional society meetings. At this meeting, the Director, GML, presented a general picture of the GML structure, after the reorganization effected earlier this year, and of administrative, fiscal, and other matters affecting the Laboratory. He then presented the GML staff scientists in attendance, each of whom described the scientific activities in his/her division.

A list of the ASB members, and members of the Board of Directors of GMI who were present at this meeting, is attached. The members were generally pleased with the presentation and expressed a desire to have more extensive meetings for more detailed program and project reviews. They also recommended that more site visits to Panama be arranged by GMI, and that attempts be made to have individual members of the ASB stop off at GML during trips to other places in Latin America.

The GMI President emphasized that it is because of fiscal constraints that more site visits have not been held at GML. When GMI budgetary affairs are improved, the involvement of the ASB in evaluating programs and projects will be enhanced. It is to be hoped that future meetings of the ASB in the U.S. can be arranged, that will be longer and more conducive to in-depth program reviews. We will be seeking advice also on how to involve students and post-doctoral fellows from more U.S. and Latin American institutions in activities at GML.

3) A subcommittee of the Executive Committee of the Board of Directors, GMI, has been working for about three months on revisions of the By-Laws of the GML. These suggested changes are to be presented to the Board of Directors at the annual meeting on March 1, 1984. The purpose of the changes is to provide for more effective business expertise and fund-raising capability on the Board of Directors, reconstitution of the Advisory Scientific Board and more utilization of its expertise in program planning and evaluation, and increased Panamanian and Latin American participation. It is proposed to separate the offices of Chairman of the Board and President, with the latter becoming a full-time employee, Chief Executive Officer, responsible for business and fund-raising.

The proposed amendments to the By-Laws will provide additional members to the Advisory Scientific Board in order to achieve a greater participation by new members from the Latin American scientific community. The Executive Committee has also approved a disciplinary subcommittee structure for the ASB in order to increase flexibility and expertise.

4) In conjunction with the above proposed changes in By-Laws, the Executive Committee has already voted "seed money" for the generation of fund-raising campaigns. The choice of an organization to start on such activities is being deferred until a new Board of Directors, with more knowledge about such practices, is elected. This will occur some time after March 1.

5) A local fund-raising effort has just been initiated in Panama. Panamanian Directors and administrative staff of GML are cooperating in this venture. Concern about the closing of GML was aroused in Panamanian circles last year because of the possibility of the loss of the U.S. federal funds which serve for core support of the Laboratory. While it is not expected that the fund-raising activities, described in Part 4 and here, will produce enough revenue to eliminate the need for the Congressional approprpriations, we hope that we will attract enough funding to enhance the scientific programs of GML, improve the physical plant, and expand educational opportunities for U.S. and Latin American trainees in the important, but neglected, field of tropical medicine.

Leon Jacobs, Ph.D.
President and Chairman of the Board

27 January 1984

# ATTENDANTS AT THE ADVISORY SCIENTIFIC BOARD MEETING
San Antonio, Texas - 7 December 1983

## ADVISORY SCIENTIFIC BOARD

PAUL C. BEAVER, Ph.D., - New Orleans, Louisiana
ABRAM S. BENENSON, M.D. - San Diego, California
FRANKLIN A. NEVA, M.D. - Bethesda, Maryland
WILLIAM C. REEVES, Ph.D. - Berkeley, California
ROBERT E. SHOPE, M.D. - New Haven, Connecticut
PAUL P. WEINSTEIN, Sc.D. - Notre Dame, Indiana
THOMAS H. WELLER, M.D. - Boston, Massachusetts
MARTIN D. YOUNG, Sc.D. - Gainesville, Florida

## BOARD OF DIRECTORS

JOHN I. BRUCE, Ph.D.- Lowell, Massachusetts
MARK T. HOEKENGA, M.D. - Glendale, Ohio
VERNON KNIGHT, M.D. - Houston, Texas
LLEWELLYN J. LEGTERS, M.D. - Bethesda, Maryland
JACK W. MILLAR, M.D. - Poolesville, Maryland
JAY P. SANFORD, M.D. - Bethesda, Maryland
EVERETT L. SCHILLER, Sc.D. - Baltimore, Maryland
WILLIAM D. TIGERTT, M.D. - Baltimore, Maryland
FRANKLIN H. TOP, Jr., M.D. - Washington, D.C.
PHILLIP E. WINTER, M.D. - Washington, D.C.
MARTIN S. WOLFE, M.D. - Washington, D.C.

## GUESTS

ROBERT TESH, M.D. - New Haven, Connecticut
JACOB K. FRENKEL, M.D., Ph.D. - Kansas City, Kansas
KARL WESTERN, M.D. - Bethesda, Maryland
BRYCE WALTON, Ph.D. - Pan American Health Organization
CRAIG WALLACE, M.D. - Bethesda, Maryland
CARLOS R. ABRAMOWSKY, M.D. - Cleveland, Ohio
HORTENCIA HORNBEAK, Ph.D. - Bethesda, Maryland

## GML STAFF

RAYMOND H. WATTEN, M.D.
WILLIAM C. REEVES, M.D.
BEDSY DUTARY, Ph.D.
HOWARD A. CHRISTENSEN, Ph.D.
JOHN L. PETERSEN, Ph.D.
F. STEPHEN WIGNALL, M.D.

## LETTER FROM CLYDE BEHNEY, OFFICE OF TECHNOLOGY ASSESSMENT

February 19, 1984

TO: Gar Kaganowich
Senate Committee on Appropriations

FROM: Clyde Behney Clyde
Hellen Gelband
Steve Bjorge

RE: Comments on Letter from GMI/GML to
Sen. Weicker, dated 1/27/84

As you requested, here are our reactions to the report of the Gorgas Memorial Institute, which GMI prepared in response to the Senate Committee report on GMI's FY84 appropriations.

In brief, our reactions are mixed: there is evidence of some attempts to address a few of the findings of the OTA study, but some of their information is vague and some findings were not dealt with at all. It is difficult to do much analysis based on a report of only two pages, therefore this memorandum will not only react to the report but also suggest areas where you may want to request further information. If you have additional questions, please let us know (we're all at 6-2070).

**OTA's Suggestions:** The OTA report contained five explicit examples of possible actions GMI/GML might take to improve the quality and relevance of its activities:

- Be more aggressive about publishing the results of their research;
- Improve the use of the Advisory Scientific Board (ASB) (e.g., to help plan the research agenda, to improve the internal peer review process, and as visiting consultants);
- Build more collaborative arrangements with universities, other countries (especially Latin American ones), and international organizations (e.g., PAHO);
- Develop strategic plans to move into innovative areas of biomedical research; and
- Develop/increase visiting scientist and fellowship programs.

**The GMI/GML Report:** The report mentions five actions taken by GMI/GML: 1) Establishment of a policy to use the ASB to review manuscripts of research papers, 2) A meeting of the ASB was held in December, 3) By-laws are being rewritten, 4) Seed money has been voted for a fund-raising campaign, and 5) A local (Panama) fund-raising effort has been started.

**OTA Reactions:** As mentioned, the report appears to reflect concern on the part of GMI/GML in dealing with the organization's future and the criticisms of OTA and GAO. The report is too general and vague, however, to provide a clear picture of what they are actually doing. It may be too early to expect more detail. On the other hand, they have had nearly half a year since the OTA and GAO reports, and longer since they knew that changes should be considered.

On our suggestion that GML scientists and management be more aggressive in publishing the results of their research: If the use of the ASB is an indication that GMI/GML has such an attitude, that is a good step. Even by itself, the use of the ASB to review manuscripts is an excellent idea, but it can not be simply a "paper policy". GMI/GML must implement it actively, and the ASB members must take the responsibility seriously. It should be an explicit requirement of membership on the ASB that its members take the time to give manuscripts a thorough critique. It would have been valuable to know the recent number of publications and active manuscripts.

The report does not discuss steps toward assuring the quality of research at Gorgas. Nor does it discuss improved mechanisms for deciding on the direction of research programs, or priority setting in research programs. The lack of a peer review system for ongoing and planned research was noted in both the OTA and GAO reports as a first order priority. The Gorgas report does not mention their plans in this area directly. Indeed, it receives only a peripheral mention, under the discussion about changes in the by-laws. The information on the ASB is too sketchy to tell if it will be used in this role.

We strongly urged consideration of increased use of collaborative arrangements with universities, other countries, and international organizations. We find no information on whether Gorgas plans to pursue such arrangements. This is a serious point, and we suggest that Gorgas be asked about it.

We found no information on Gorgas's plans to move more centrally into developing areas of science, as mentioned in the OTA study. Perhaps Gorgas could be requested to provide information on the directions in which its research program is moving.

No mention is made of visiting scientist activities, and fellowship activities are only mentioned in regard to "seeking advice [of the ASB] on how to involve students and post-doctoral fellows..." It is hard to believe that Gorgas has not put more thought and energy into these possibilities than is reflected in the report. In fact, we suspect they have, but it does not show up in their report.

Too little information was provided about the ongoing revisions of the GMI/GML by-laws. However, the goals of the revisions (more effective business and fund-raising expertise, increased Latin American participation, better use of the ASB) certainly fall in line with the OTA and GAO suggestions. We suggest that you ask Gorgas for specifics on what the changes are or are planned to be, how they are expected to impact on the problems, and the timetable for implementation. Without such information it is impossible to evaluate them.

One proposed by-law change is to create a full-time position, Chief Executive Officer. It is not clear, and not supported in the report, that this is the best, or even a desirable, option. A more detailed account of the expectations attached to that position would help evaluate the potential of such a change. If it results in more collaborative arrangements being set up, more funds being raised, and more active relationships with U.S. and international organizations (for both scientific and financial interaction), then the move may be a good one. If, however, the new position is salaried and increases the GMI (Washington, D.C.) overhead expenses to the extent of a new salary, support services, etc., without overcompensating fiscal returns, then questions must be raised about the goal of such a move.

In the report, fund-raising activities appear to be discussed separate from scientific issues. Would such activities include helping individual GML scientists apply for grants and contracts? Such assistance might be helpful, but it is impossible to tell what Gorgas has in mind from the discussion in the report.

The last action mentioned by Gorgas is a Panamanian fund-raising effort. Even if this effort has modest results, it is an excellent idea. Perhaps, if the level collected does turn out to be rather modest, that it could be used to establish a fellowship fund for Panamanian scientists to work at Gorgas, or for a non-Panamanian fellow or visiting scientist to be supported under "the Sponsorship of the Panamanian People."

**In Summary:** There is a lack of detail in the report. A couple of excellent ideas were mentioned. Several of the OTA suggestions were addressed, albeit in a vague manner. Others were not covered. In general, no details are given, and no timetable for planned actions. Other than a few actions that appear to be in the right direction, there is not a great deal in this report to evaluate.

## FUNDING OF GORGAS MEMORIAL INSTITUTE

Senator WEICKER. Apparently money seems to be a major problem with Gorgas and the uncertainty there will be a regular flow of Federal funding. What is being done to stabilize that situation?

Dr. WALLACE. The Gorgas Memorial Institute is planning a fundraising effort. We at the Fogarty International Center are a conduit for their appropriated funds and we have a very close relationship with the Gorgas Memorial Institute. We are attempting to assist them to strengthen their scientific program, so that they can attract additional funds. They do have the same opportunity to apply for regular project grants of the National Institutes of Health that other institutions have. Both Gorgas and the American University in Beirut are two overseas institutions that do not have the restraints that other foreign institutions do in requesting funding from the National Institutes of Health.

## COORDINATION WITH NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Senator WEICKER. How do you, Dr. Wallace, and Dr. Krause's institute—how do you two coordinate? Do you coordinate? It seems to me there's a great similarity.

Dr. WALLACE. Yes; we do coordinate. Actually, I had occasion, when I spoke with Dr. Krause before coming to NIH, to indicate my shared personal interest with the National Institute of Allergy and Infectious Diseases, since I am, by scientific training, interested in infectious disease and tropical medicine.

We also have a very close relationship with the international coordinator at the NIAID, as well as with Dr. Jordan, who is in charge of the vaccine program at the NIAID. However, the programs of the Fogarty International Center are broader in that we coordinate all biomedical research areas at the international level.

Senator WEICKER. What do you do that is different from what Dr. Krause's institute does?

Dr. WALLACE. The Fogarty International Center is the focus of international activities at the NIH. We utilize and coordinate the scientific expertise within the various categorical institutes to bring resources to bear on international areas. We are the liaison, and serve as a channel to stimulate and facilitate scientific exchange in the international research community. Dr. Krause and his scientists play a very integral part in certain of the conferences I mentioned previously.

We have the primary responsibility at NIH to award research fellowships to foreign scientists to come and work in the United States. We also award senior international fellowships which provide opportunities for senior American scientists to conduct research abroad. The information that is exchanged by those scientists is a contribution to the activities of all of the National Institutes of Health.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record. And I thank you very much, Dr. Wallace.

And I have copies of the reports on the Gorgas matter which will be included in the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You have already heard me go over the shortcomings of the fiscal 1985 NIH budget--overall increase, reduction in new grants, under-funding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget--or were you simply handed a number and told to find ways to live within it?

Answer: Because I was only recently appointed as Director of the Fogarty International Center, I, personally, had no input in developing this budget request. However, my predecessor, along with the other BID Directors, was consulted at the time of every major submission in the budget process.

Question: What is the impact of the budget request on your Institute, and what will it do to the scientific momentum you are trying to maintain?

Answer: We will be able to carry out the missions of the Fogarty International Center within the budget request but at a reduced level of program activity. In particular, the Advanced Studies Program cannot be further developed, and the number of awards in the International Research Fellowship and Senior International Fellowship Programs will be reduced from the 1984 level although the average size of these awards will increase.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984?

Answer: It would require an additional $520,000 to maintain the Fogarty International Center at the current services level.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction--and where will you take it? With what effect on research?

Answer: Our share of the proposed reduction is 3 full-time equivalent positions; all will be taken from Research Management and Support where all 62 FIC positions are allocated. It is difficult to assess the precise impact this reduction will have on our programs. FIC will attempt to implement the reduction in a way that minimizes the impact on work in progress and on the effective management of our organization.

### GORGAS MEMORIAL LABORATORY

Question: Last year the Administration tried to cut off funding for the Gorgas Memorial Laboratory in Panama--a facility dedicated to research on tropical diseases. Congress rejected the proposal after reviewing studies that confirmed the importance of maintaining Federal support for the laboratory. However, the studies by GAO and the Office of Technology Assessment did suggest that Gorgas strengthen its financial base, do a better job of scientific review of projects, do long-range planning and do more collaborative work with American universities. To what extent is Gorgas responding to the recommendations for improvement?

Answer: The Gorgas Memorial Institute has recently submitted a report to Congress on initial steps planned in this regard. It has begun implementing those steps in actions that its Board of Directors took at its Annual Meeting on March 1. Furthermore, GMI and the Fogarty International Center will be working very closely on matters of planning scientific review and expanding collaborative relationships with universities. GMI/GML already have formal agreements with Louisiana State University and Michigan State University, and just recently a verbal agreement was reached with officials of the University of Alabama at Birmingham. A formal memorandum establishing a collaborative relationship is being prepared. A schedule of technical visits to the Laboratory in Panama is being developed at this time. In the area of fund-raising, GMI has just selected a contractor to lead this effort.

Question: We note there is some delay in the Laboratory relocating to new quarters in Panama City and that this may be a barrier to greater collaborative work. What is the problem here?

Answer: Some delay is being experienced in contractor renovation work which must be done within the main laboratory building, such as with the ventilation system, to accommodate the virology work that is to be relocated there. Relocation is being handled in phases, and research activities are able to continue for the most important scientific areas.

Question: Money seems to be a major problem with Gorgas--money and the continued uncertainty there will be a regular flow of Federal funding. What are you doing to stabilize this situation and to see to it that the organization is not starved financially?

Answer: The Fogarty International Center is requesting funds for FY 1985 to maintain the core support by the Federal Government. We are operating on the assumption that this level of funding will continue. This core support is not intended to provide all the resources needed to sustain a major research effort--it does allow for the maintenance of the physical plant and key staff, thus providing institutional core support to which additional resources may be attracted. The constraints on funding for the Gorgas Institute/ Laboratory core grant are comparable to programs of the Fogarty International Center and to all NIH support of other extramural research centers and institutions.

## DISEASE CONTROL ADVANCES

Question: The Fogarty International Center, through its Advanced Studies Program, has made a strong effort to focus world attention on the potential for eradication of certain diseases. What major advances in disease control have been accomplished through Fogarty programs over the past five years? What has been the economic benefit to societies and developing countries of these advances?

Answer: The Fogarty International Center's efforts to focus world attention on the potential for specific disease eradication began in May 1980. A workshop at the NIH evaluated a number of infectious disease candidates. Three were chosen as likely candidates for improved control and potential eradication. International symposia were held on two diseases: measles in the spring of 1982, and paralytic poliomyelitis in the spring of 1983. The third meeting, scheduled for this April, will address yaws and other endemic treponematoses.

The 1982 measles conference has had a significant impact internationally. It has helped stimulate a number of nations--including the Soviet Union, Sweden and Finland--to make the elimination of measles a national health priority. A still larger number of countries, both at the national level and throughout the health care system, have recognized the importance of increasing immunization rates and have instituted appropriate immunization campaigns. France has initiated such a campaign within the past year, and the United Kingdom is attempting to improve its relatively low immunization numbers.

The consensus arising from the 1982 conference on measles was that, scientifically, measles can be eradicated. The United States hoped to eliminate measles by the end of 1983; however, over 1,400 cases occurred last year. These were seen primarily in the college-age population who missed immunization in the 1960's when immunization rates declined far below previous levels. Imported cases of measles have also proved to be a problem in spreading the disease. FIC is planning a follow-up review of research needs and vaccine strategies for measles. Increasing control of measles will also clarify the relationship between acute measles and those chronic neurological diseases such as subacute sclerosing panencephalitis (SSPE) caused by persistent infection with measles virus, as well as those diseases where there is some suspicion of relationship to measles virus infection, for example, multiple sclerosis.

In the developing world, approximately one million deaths per year result from measles infections. Few other diseases preventable through vaccination account for such widespread morbidity and mortality. The economic benefit of reducing this toll through immunization is widely accepted. It is estimated that, for every dollar spent for measles immunization, ten dollars are saved in health care costs. The cost-benefit to the United States also depends on actions taken by other governments to control the highly infectious measles virus. Measles vaccination programs are having a demonstrable benefit worldwide. In 1978 over 4,000,000 cases were reported; this number fell to 2,900,000 cases in 1980; and in the Americas, most countries reported fewer cases of measles in 1983 than in 1982.

The "International Symposium on Control of Paralytic Poliomyelitis," held in the spring of 1983, reached agreement that eradication is not feasible in this century, but remains a distant goal, principally because of administrative barriers. The eradication of polio is not the highest health priority in nations with very serious health problems and limited resources. These resources are being used to address diseases with higher mortality and morbidity. An important result of the polio conference, however, was to demonstrate that paralytic polio is more of a problem than most nations realized, particularly in the developing world. Although paralytic polio has been essentially eliminated in the United States, 65 percent of the world's nations are burdened with this disease.

Just this month, the FIC is bringing together experts from 20 countries to consider the eradication of yaws, a nonvenereal bacterial disease mainly affecting children in the poorest, often most remote areas (e.g., Papua New Guinea, rural West Africa, Indonesia). A cure for yaws is achieved by a single intramuscular injection of long-lasting penicillin. Since the numbers afflicted are relatively small, but increasing, and resistance to the antibiotic has not yet arisen, but may, consideration of yaws as a potentially eradicable disease is timely. This meeting will document the prevalence of yaws, particularly in the Sahelian Region and West and Central Africa where the situation is precarious. Over the last two decades, untreated cases have increased dramatically when mobile health care teams were assigned activities of a higher priority, and in some areas the mobile health teams were actually disbanded.

Question: What progress has been made over the past year to organize a program to prevent congenital rubella?

Answer: In March of 1984, the Fogarty International Center sponsored a meeting on the "Prevention of Rubella Birth Defects." Although congenital rubella syndrome was not considered a candidate for eradication, improved control is needed because cyclic epidemics occur in a number of nations. Progress in the control of congenital rubella was documented, and important new information regarding the effectiveness and limitations of various prevention strategies was discussed.

Question: What international symposia on this subject have you organized?

Answer: An international symposium on the "Prevention of Congenital Rubella Infection" (and subsequent rubella birth defects) was held in Washington, D.C., in March of 1984. Scientists, clinicians, and public health officials from 25 countries attended this conference.

Several significant results were reported. Vaccine strategy is very important. The United States chose universal vaccination of children and broke the chain of epidemics: 20,000 cases of birth defects in the last epidemic of 1964-1965 were reduced to 7 affected births in 1983. Selected vaccination of pre-adolescent girls and young women has not, in general, worked in most countries utilizing a selective vaccine strategy; higher rates of immunization, up to 90 percent, are needed in these countries. Great Britain has had outbreaks in 1978-79 and 1981-82. It was also noted that a country cannot switch from a selective to a universal vaccine strategy midstream; to do so could increase, rather than decrease, the risk of congenital rubella syndrome.

The rubella vaccine was demonstrated not only to be long-lasting but safe, even for inadvertently vaccinated pregnant women. Approximately one-third of therapeutic abortions for rubella are for vaccine-associated cases. Evidence was presented that several hundred women known to have been vaccinated during pregnancy carried to term, and all resulted in normal births. There is a small theoretical risk of congenital defects, and vaccination three months before or after conception remains contra-indicated. Australia has recommended against rubella vaccine-associated abortions, and other nations are expected to follow suit.

Rubella vaccination programs are expected to prevent 10,000 cases of deafness by the end of this century, with estimated savings of over $2 billion.

Question: What disease management and eradication efforts do you have underway on polio, yaws, malaria, and tropical parasitic diseases? Which of these is the most promising?

Answer: Just this month, the Fogarty International Center is holding international conferences on "Contended Issues of Immunity to Schistosomes" and "Yaws and Other Endemic Treponematoses."

An estimated 200 million people are estimated to be infected with schistosomiasis, a parasitic disease, which is estimated to affect over 2 million people, mostly in developing countries in tropical regions. Prevention of endemic schistosomiasis would be much easier to accomplish if a human vaccine against the parasites of "snail fever" became available; but, how realistic is this goal, and how should research be focused toward its attainment? To answer these questions, the Fogarty International Center in cooperation with the Edna McConnell Clark Foundation and the World Bank/UNDP/WHO Special Programme for Research and Training in Tropical Diseases is bringing together this month 35 U.S. and international scientists for discussions at NIH. Discussions at this conference will center on those issues on which there is uncertainty or contradictory evidence, in order to formulate plans for definite future studies.

In animal experiments, both live attenuated and "defined antigen" vaccines against schistosomes are being developed. Live vaccines have already been successfully applied to disease reduction in endemically infected cattle. With the advent of effective schistosomicidal drugs and of experimental immunizing procedures, more direct approaches have become feasible for the improved control of schistosomiasis. The essential question - does human immunity against human-adapted schistosomes exist and what is its magnitude - will be vigorously discussed.

An international symposium to be held later this month will assess the global impact of yaws (a nonvenereal, spirochetal skin infection occurring primarily in tropical regions) and determine the effectiveness of control strategies.

Yaws mainly affects children, is easily recognizable and curable, yet remains a major cause of pain, disfigurement, and disability in the countries affected. Control strategies and the potential eradicability will be discussed.

At the conference on control of paralytic poliomyelitis held in the spring of 1983, the consensus was that polio can be controlled worldwide with the use of the Sabin and Salk vaccines, but that eradication of polio (elimination of the viruses) is not feasible at this time. This remains, however, a distant, though achievable, goal. It appears that the main obstacle to timely eradication of paralytic polio is the lack of political will, coupled with disease priority decisions in some nations.

In the field of malaria, there is some excitement concerning the potential for making a vaccine; further research and clinical trials will be undertaken by other appropriate agencies.

The disease most promising for improved control and potential eradication is yaws. It is curable by penicillin, and world attention will be focused on potential eradication. Scientists from twenty nations are represented on the scientific program for the international symposium to be held this month.

## BILATERAL AGREEMENTS

Question: Over the past two years, there has been a steady increase in the number of bilateral agreements between NIH and foreign governments. How many bilateral agreements is FIC planning for next year? Which ones do you consider to be the most significant and promising?

Answer: The FIC is anticipating NIH involvement in bilateral agreements with Canada, Belgium, Austria, Thailand and Korea. While we consider all of the planned agreements to be significant and promising, those with Korea and Thailand are among the most significant in terms of opening new areas of cooperation with these countries to advance knowledge in biomedical sciences in areas of mutual interest and benefit. There is considerable informal scientist-to-scientist collaboration already ongoing in such countries as Canada and Belgium. The planned agreements would serve to supplement these activities.

## COLLABORATIVE EFFORTS

Question: The subcommittee is aware of collaborative research efforts underway with a number of countries. Presumably we provide a lot of technical expertise in medicine to foreign countries and that helps our international relations. What do we get in return?

Answer: We provide technical expertise in the field of biomedical research to foreign countries in conjunction with collaborative research efforts as well as other bilateral and health scientist exchange activities. This is not a one-way transfer of expertise. It is a sharing of technical resources and expertise resulting in many scientific benefits to the United States. Biomedical research cannot be conducted by any single country in isolation. Because most health and disease problems are universal, many biomedical advances have occurred as a consequence of this sharing of information.

Question: What sort of work do you do with the People's Republic of China, India and Japan?

Answer: NIH cooperates with China under three agreements covering basic, clinical and epidemiological studies in the areas of infectious and parasitic diseases, cancer, cardiovascular diseases, child health and nutrition, environmental and occupational health, immunology, medical genetics, mental health, reproductive physiology and family planning, and neuroscience. Other joint activities involve public health and health services research and medical information. NIH also awards grants, contracts and fellowships to Chinese scientists on a competitive basis and supports the participation of Chinese scientists in the NIH Visiting Scientists and Guest Researcher Programs.

NIH has had a long history of collaboration with India in a variety of areas. Most recently, under the Indo-United States Science and Technology initiative sponsored by Prime Minister Indira Gandhi and President Reagan, collaborative projects have been initiated in the areas of infectious diseases (leprosy/tuberculosis, malaria, filariasis), blindness (cataracts, nutritional blindness, and Eale's disease) and reproductive physiology. India also participates in Fogarty International Center's International Research Fellowship Program, the NIH Visiting Scientists Program, the Special Foreign Currency Program, and the competitive grants and contracts programs.

NIH has five different cooperative agreements with Japan covering cooperation in the fields of cancer, vision research, parasitic and infectious diseases, cardiovascular diseases, toxicology, and medical information. Under the new anticancer program in Japan launched by Prime Minister Nakasone, opportunities will be created for scientists from the United States, including those in the early stages of their careers, to conduct research in Japan for 1-2 years and for senior scientists from the United States to lecture in Japan. This activity will be fully supported by the Japanese side. The programs are being developed jointly by Japan with the National Cancer Institute and the Fogarty International Center.

NIH also awards research grants, contracts, and fellowships to Japanese scientists and supports their participation in the Visiting Scientists Program.

Question: We hear reports that China is making considerable progress in the treatment of certain cancers. How credible are these advances?

Answer: The primary focus of the National Cancer Institute's cooperation with China is in epidemiologic rather than clinical studies. The NCI's Division of Cancer Treatment is not aware of any specific new advances in cancer therapies in China; however, the Chinese have traditionally used natural products as anti-neoplastic agents. It is very important that we work closely with the Chinese to verify and compare results.

## NATIONAL LIBRARY OF MEDICINE

## STATEMENT OF DR. HAROLD M. SCHOOLMAN, ACTING DIRECTOR

**ACCOMPANIED BY:**

**DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**KENT A. SMITH, DEPUTY DIRECTOR**

**ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. Next to come before the subcommittee is the National Library of Medicine. The Library is the Nation's primary resource for biomedical literature and for the development of technology to store or distribute that literature. The request is for $51 million, which is $7 million more than the amount provided for the current fiscal year.

Dr. Martin Cummings, the long-time Director of the Library, recently retired and has been replaced by Dr. Schoolman, who is Acting Director. We welcome you and please proceed.

[The statement follows:]

## STATEMENT OF DR. HAROLD M. SCHOOLMAN

I am most pleased to be here today to testify regarding the National Library of Medicine budget request. In this, my first appearance before the subcommittee, I would be remiss if I failed to note the retirement of Dr. Martin M. Cummings, who has appeared before you for the past twenty years as Director of NLM. Under his leadership, the National Library of Medicine flourished. The scope of its programs increased dramatically to include extensive outreach through the Regional Medical Library program, which made available to health practitioners throughout the nation not only the resources of their national medical library but also those of virtually every medical library in the country. This was accompanied by a significant grant program to improve the resources of the nation's medical libraries and by new and vigorous intramural and extramural research programs in "Medical Informatics." The creation of a research and development program and the construction of the Lister Hill National Center for Biomedical Communications now offers the nation a unique resource for the application of the latest computer, communications, and audiovisual technologies to health problems. Perhaps the most remarkable achievement was the development and operation of an online health science information network that provides service throughout the nation.

The National Library of Medicine is a complex organization that performs comprehensive and essential library functions. By statute, NLM has the responsibility to collect, organize, index, catalog, and make available the world's biomedical literature. No other organization, public or private, duplicates these comprehensive integrated information activities.

Publication is an essential part of the research process. It is the mechanism through which results are announced and findings are submitted to the critical review of scientific peers. Without it the nation's vast investment in the generation of new biomedical information could not be justified. The National Library of Medicine is the linchpin in this process, not only accumulating the vast body of published information but filtering it and providing selective access so that relevant research results are available quickly for application at the bedside.

## Dissemination of Information

NLM continuously and comprehensively acquires new and retrospective published information to ensure that its collections meet the needs of the nation's health sciences professionals. Presently, the Library's collection consists of over 3.1 million books, journals, technical reports, theses, pamphlets, manuscripts, microfilm, and pictorial and audiovisual materials. The NLM's collection provides the basis for its service programs and serves as a backup for health sciences libraries throughout the country.

The Regional Medical Library (RML) network is designed to improve reference services, document delivery, resource sharing, basic skills of library staff, and local self-sufficiency. In the 15 years since the RML network was formed, more than 15 million books and journal articles have been loaned and 10 million computer searches have been provided for health professionals at member institutions.

NLM has pioneered MEDLARS (Medical Literature Analysis and Retrieval System), a computerized bibliographic information system. Originally developed to computerize the preparation of Index Medicus, the primary source for medical bibliographic information, MEDLARS has evolved into a family of over 20 databases and datafiles accessible online from computer terminals at more than 2,100 institutions nationwide.

Yet, Mr. Chairman, despite these successful programs to disseminate research results to the nation's clinicians and researchers, the National Library of Medicine still faces a growing challenge in this rapidly changing age. The basic problem remains how to provide the health practitioner with the information needed, when it is needed, and in a format that is useful. Two programs, of the highest priority, are being supported by the Medical Library Assistance Act (MLAA) program, to attempt to meet this challenge. The first is called Medical Informatics, and the second is Integrated Academic Information Management Systems (IAIMS).

## Medical Informatics

Medical Informatics is an extramural program of research training, career development and research support to develop a cadre of bright, young career investigators to explore fundamental processes involved with the organization, utilization, and validation of medical knowledge. This NLM program, formerly known as Computers-in-Medicine, began in 1973 and has supported over 350 trainees in this specialized discipline. Much of the research training fostered by NLM has focused on developing computerized systems with which human users may consult interactively, much in the same way that physicians now consult with their colleagues. This is the only program within NIH that emphasizes research in the medical information sciences.

A recent National Science Foundation study reached two significant conclusions regarding computing in higher education: "There is a major crisis in training computer scientists," and "other nations have recognized the role of computing in the development of their national plans and are investing in research and training with a focus and on a scale not found in the U.S." The conclusions apply with special force to the health sciences. To help meet the growing need for qualified, talented investigators who are well-equipped to address fundamental issues in the management of health knowledge, NLM will continue its Medical Infomatics program in FY 1985 by funding an estimated four new research training awards.

## Integrated Academic Information Management Systems

The second high priority program I wish to highlight, Integrated Academic Information Management Systems (IAIMS), was begun last year by NLM and stimulated by an NLM-supported study by the Association of American Medical Colleges (AAMC). This study pointed out the need for academic health sciences centers and hospitals to take immediate steps to find new and better ways to cope with the flow of information that must be managed to operate efficiently in the modern electronic age. The study recommended that NLM support prototype information network systems within such institutions.

The basic IAIMS concept is to use computer and communications technologies to bring together into one system the myriad sources of information now widely scattered throughout a major health science center. A typical scenario envisions the health professional, with a small desk top terminal, having rapid and easy access to a variety of computerized files--calling up patient records, ordering laboratory tests and reviewing their results, examining the professional literature, searching remote files such as a tumor registry in another state, consulting clinical decision-making systems, monitoring the progress of students, and communicating with his colleagues.

NLM is using several mechanisms to support IAIMS activities. The process of prototype development began in 1983 with the award of planning contracts to Columbia University, Georgetown University, the University of Maryland and the University of Utah. These are cost-sharing awards that result in contributions by the contractors of almost $800,000. A similar contract was issued in early 1984 to the Oregon Health Sciences University. These five contract awards establish a foundation for future advances and experiments in this important area.

## Library Operations

This activity, to which one-half of the NLM budget is devoted, consists of three primary functions: (1) acquisition and preservation of the biomedical literature, (2) creation and dissemination of bibliographic data; and (3) document delivery and reference. Some statistics from FY 1983 help illustrate the scope of these tasks:

- NLM acquired 27,000 books and audiovisual materials, 138,000 serial pieces representing 23,000 individual titles and 46,000 modern manuscripts.
- More than 18,000 books and audiovisuals were cataloged.
- 310,000 journal article references were added to the MEDLARS family of computerized databases and datafiles.
- Requests for 211,000 interlibrary loans were processed.

With the ever-increasing volume of biomedical literature, NLM must rely more and more on computers to aid in handling the workload. An enhanced system, known as MEDLARS III is well along in its development. MEDLARS III is intended to automate, improve, extend, and integrate such labor-intensive internal library operations as ordering, receiving, and cataloging materials.

## Lister Hill Center

The Lister Hill National Center for Biomedical Communications is NLM's intramural research and development component. The Center, established by Congress in 1968, has conducted a series of pioneering experiments in biomedical communications and has developed a number of valuable prototype systems, including the original version of the MEDLINE (MEDLARS Online) database. Last year, a successful reorganization was effected, and under the leadership of a new director, the Center is developing new program directions including research into the human factors (such as man-machine interactions) involved in the transfer of biomedical information; automated indexing to ultimately improve the timeliness and quality of indexing data; electronic document preservation, storage, and retrieval using optical videodisc technology; and computer assisted instruction research to benefit medical education.

## Toxicology Information

The Toxicology Information Program (TIP) was established at the National Library of Medicine in 1967 as the result of a Presidential directive. The objectives of TIP are to: create computerized databases in the area of toxicology, pharmacology, and environmental health, and to provide toxicology information products and services to the scientific community. These services are implemented through a variety of online information retrieval services, query response services, and interagency collaborative projects. Utilizing funds provided under the "Superfund Act," existing NLM online databases such as TOXLINE, CHEMLINE and the Toxicology Data Bank (TDB), are being expanded with information relevant to chemicals likely to occur in waste dumps or be involved in chemical accidents. The usefulness of these enhanced NLM databases was demonstrated during the recent "Tire Fire" environmental emergency in Winchester, Virginia, when TDB was queried to provide data and information on the toxic chemicals produced by the fire.

## Summary

The amount of new information resulting from the Federal investment in basic biomedical research is expanding rapidly. Fortunately, recent developments in information-handling technology afford us the opportunity to develop improved systems to bring these advances directly to our physicians and researchers. The two high priority programs I have highlighted for you today, Medical Informatics and Integrated Academic Information Management Systems can help the Library and the entire nation's information community to successfully meet this challenge.

Mr. Chairman, the request for the National Library of Medicine for FY 1985 is $51,320,000, an increase of $1,100,000 over the comparable FY 1984 level. I shall be pleased to answer questions and supply additional information for the record.

## Biography of Dr. Harold M. Schoolman

POSITION : Acting Director, National Library of Medicine

BIRTHPLACE AND DATE : Chicago, Illinois, January 14, 1924

EDUCATION : B.S., University of Illinois, 1944
M.D., University of Illinois College of Medicine, 1950

Certified American Board of Internal Medicine

EXPERIENCE

1983-present : Acting Director, National Library of Medicine
Concurrent with:

1977-present : Deputy Director for Research and Education, National Library of Medicine

1970-present : Clinical Professor, Georgetown University School of Medicine

1972-1977 : Assistant Deputy Director, National Library of Medicine

1971-1973 : Special Assistant to the Director for Medical Program Development and Evaluation, National Library of Medicine

1971-1973 : Attending Physician, D.C. General Hospital/Georgetown Service, Washington, D.C.

1968-1976 : Attending Physician, Veterans Administration Hospital, Washington, D.C.

1967-1970 : Director, Education Service, Central Office, Veterans Administration, Washington, D.C.

1963-1967 : Acting Associate Chief of Staff for Research, Veterans Administration Hospital, Hines, Illinois

1962-1967 : Chief, Biostatistical Research Support Center, Veterans Administration Hospital, Hines, Illinois

1961-1967 : Chief, Hematology Research Laboratories, Veterans Administration Hospital, Hines, Illinois

1960-1965 : Clinical Assistant Professor, University of Illinois Department of Medicine

1960-1962 : Section Chief, Veterans Administration Hospital, Hines, Illinois

1958-1960 : Associate, University of Illinois Department of Medicine

1959-1960 : Special Fellowship: NIH Division of General Medical Sciences - London School of Hygiene and Tropical Medicine, Department of Medical Statistics, London, England

1958-1967 : Attending Physician, Cook County Hospital

1958-1967 : Professor, Cook County Graduate School of Medicine

1957-1959 : Liaison with Pathology, Department of Medical Education of the Cook County Hospital

1957-1959 : Coordinator of Clinical-Pathologic Research and Education Department of Pathology of the Cook County Hospital

1955-1959 : Research Associate, Hektoen Institute for Medical Research of the Cook County Hospital

1954-1967 : Associate Attending Physician, Research and Education Hospital-Department of Medicine

1954-1958 : Associate Attending Physician, Cook County Hospital

1954-1958 : Instructor, University of Illinois Department of Medicine

1954-1958 : Associate Professor, Cook County Graduate School of Medicine

1952-1954 : Clinical Assistant, University of Illinois Department of Medicine

PROFESSIONAL SOCIETIES : American Medical Association
American Federation for Clinical Research
Sigma Xi
American Association for the Advancement of Science
American Association for Cancer Research
Society for Experimental Biology and Medicine
American Hematology Society
American College of Physicians (Fellow)
Royal Society of Medicine (Associate)
Central Society for Clinical Research
Chicago Society of Internal Medicine
Chicago Blood Club
American Statistical Association
The Biometric Society
American Medical Association (Advisory Committee on Graduate Education)
American College of Physicians
(Audiovisual Committee)
(Telecommunication Committee Chairman)
(Educational Policy Committee)

AWARDS : University of Illinois Federal Employee Alumnus of the Year, April 4, 1975
DHEW Superior Service Award, June 9, 1975
NIH Director's Award, September 29, 1983
NLM Director's Honor Award, September 30, 1983

SUMMARY STATEMENT

Dr. SCHOOLMAN. Thank you, Mr. Chairman. I have with me Mr. Smith, who is the Deputy Director of the Library.

Mr. Chairman, the Library is a public institution whose role is vital if the Nation is to reap the full benefit of its investment in biomedical research. Publication is an integral part of the research process. It is essential not only to announce research results, but to subject them to the critical review of scientific peers.

This provides an orderly process for careful quality control to assure that only those truly beneficial and verifiable results are applied at the bedside.

Without announcement, publication would have little value, for the explosion of biomedical literature has made it virtually impossible to be aware of and locate information without secondary services.

The first of these secondary services in biomedicine was the product of the genius of Dr. John Shaw Billings when, as Director of the National Library of Medicine's antecedent, the Army Medical Library, he produced in 1879, the "Index Medicus."

This universally recognized index to the biomedical literature has been published continually, and access to its contents have been markedly facilitated and enhanced by computerized publication and online access to its contents.

Thus the Library, through its products and services, occupies a pivotal role in the research process, without which that process itself would be seriously impaired and the utilization of the fruits of the research effort and investment would be markedly limited.

To carry out these important responsibilities requires not only the intellectual input of the superb Library staff, but also a constant awareness and utilization of developing computer and communications technologies and continuing research in the problems of information processing. The basic challenge remains to provide the health practitioner with the information needed, when it is needed, and in a useful format.

NLM's modest investment in research and research training in medical informatics, the term applied to this field of inquiry, is one answer to this challenge. This program of research training, career development, and research support can develop a cadre of bright, young career investigators to explore fundamental processes involved with the organization, utilization, and validation of medical knowledge. The development and fostering of such centers of excellence in our major academic institutions is key to improving clinical decisionmaking.

In another related important effort, NLM is supporting the development in academic health centers of what are called integrated academic information management systems. These systems, called for in a study conducted by the Association of American Medical Colleges, envision the health professional with a small desk top terminal, being able to access all of the relevant information to his clinical decisionmaking from a single integrated system.

Mr. Chairman, I have touched only briefly on several items I thought might be of interest, and I'd be pleased to answer any questions you may have.

## BILL LANGUAGE

Senator WEICKER. Thank you, Dr. Schoolman. Last year the committee informed the Library we were not interested in dealing with authorizing language on the Labor-HHS appropriations bill. Your new budget, however, includes what appears to be authorization language designed to increase our revenue from Library users. Would you please explain to the committee why this appears in this request?

Dr. SCHOOLMAN. I believe Mr. Itteilag can give a more knowledgeable answer than I to your question.

Mr. ITTEILAG. Regarding the substance of your question, Mr. Chairman, the administration continues to believe that whether receipts that are or would be generated by sale of the Library's materials be returned to the Library or returned to the Treasury is not, in our view, an authorization matter. It's a matter which clearly the Appropriations Committee has, in the past, decided in various appropriations, and can determine, if it is desired, in this appropriation.

We have not offset the budget of the National Library of Medicine, however, in anticipation of these revenues.

Senator WEICKER. So you feel it might be a legitimate situation.

Mr. ITTEILAG. I think the principle of returning receipts to this appropriation as compared to the Treasury is one that the Appropriations Committee can embrace, if they so desire. You don't need, in my view, any further authorization language to do that, unless there were some prohibition in the authorizing statute.

Mr. KAGANOWICH. You said you're not offsetting the Library budget with the authorizing language in the budget. Are you proposing a $10 million increase in the budget—in the Library budget, as a result?

Mr. ITTEILAG. No; we're not. What we're saying is, that for this particular year, for fiscal year 1985, since it is very uncertain as to how much, if any, significant amount of the $10 million would be generated, that we would just see what happens, and then I think it's fair to say—although I don't know that this has been done specifically within the executive branch—that if Congress would approve this idea, and once we had some further degree of certainty as to how much money we are really talking about, then in future years, consideration would be given to offsetting the total budget authority that we would be requesting. But I think that involves some decisions that have really not been discussed in detail within the Department and have really yet to be made.

## NLM DIRECTOR'S JOB

Senator WEICKER. Dr. Schoolman, as we are aware, Dr. Cummings has retired from the Director's job, and you are filling in on an active basis. What is the timetable for bringing a new director on board?

Dr. SCHOOLMAN. I believe I ought to defer to Dr. Wyngaarden.

Dr. WYNGAARDEN. We have just finished the first round of interviewing of the candidates by the search committee, and we are having another meeting this afternoon to narrow that list to a list of finalists. We would expect to have an opportunity to approach the candidates or candidate of our choice within a few weeks.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. There will be further questions for response to the record, and I thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget--small overall increase, reduction in new grants, underfunding of grants, level funding of research centers, cutbacks in training, etc. To what degree were you consulted in the formulation of your budget--or were you simply handed a number and told to find ways to live within it?

Answer: The NLM participates in the budget development and review process. Some latitude was provided in distributing our resources within the allocation given. General guidelines were provided by OMB, HHS, PHS, and NIH.

Question: What is the impact of the budget request on the Library and what will it do to the momentum you are trying to maintain?

Answer: The FY 1985 budget request permits the Library to continue its programs and services at essentially the current rate. However, at this budget level we could not take full advantage of the opportunities available in the Medical Informatics and Integrated Academic Information Management Systems programs.

Question: How much additional funding above the budget would be required in Fiscal 1985 to maintain your institute at the same level of effort as in Fiscal 1984?

Answer: The NLM would need an additional $1.4 million above the President's budget to maintain its programs at the FY 1984 level of effort.

Question: The budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction--and where will you take it? With what effect on research?

Answer: Our share of this reduction is 24 FTE's. Two functions would be affected: the provision of biomedical information services, and research and development programs. However, it is difficult to assess the precise impact of the reduction at this time. We will attempt to make the reductions in a way to minimize the adverse impact on our programs.

### NLM DIRECTOR'S JOB

Question: Dr. Schoolman, we're aware that Dr. Cummings has retired from the Director's job and that you're filling in on an acting basis. What is the state of the search for a new director? What is the timetable for bringing a new director on-board?

Answer: As previously indicated by the Director of NIH, interviews with candidates recommended by the Search Committee have been conducted. It is my understanding that Dr. Wyngaarden expects to approach a candidate or candidates of his choice within a few weeks.

Question: I assume things are on "hold" in the meantime, or are you doing some long-range planning anyway?

Answer: The Library is continuing to function in a normal fashion, including engaging in long-range planning activities to develop necessary library and information services for the biomedical community.

PRICING POLICIES

Question: For several years, your competitors in the private sector have claimed that the Library's low rates for its computer services were undercutting their business. You were supposed to be doing a study of the matter. Where does the dispute presently stand and has any consideration been given to a two-tiered pricing system that charges more to profit-making companies and less to the non-profits?

Answer: The Department has recently conducted a study of MEDLARS pricing. The study concurs with the Library's current policy of recovering full access costs, but requests the NLM Board of Regents to reexamine the issue of differential pricing by type of user.

Question: Where does your Board of Regents stand on this matter since the Board has a good deal of say in Library activities?

Answer: By law, the Board of Regents have the responsibility of advising the Secretary on the pricing of NLM products and services. The Board will discuss the issue of differential pricing at their next meeting, on May 24, and then make their recommendation.

Question: We're told that the American Medical Association and General Telephone and Electronics are offering a new clinical literature database to doctors. Would such a database supplant any of your services, such as MEDLINE which is your largest and most frequently used service?

Answer: NLM is supportive of the AMA/GTE network which has the potential to improve biomedical communications to physicians and other users through the use of modern technology. The database service they offer is complementary to ours. The NLM databases could also be made available through this network, if AMA/GTE were to lease them from us, as two commercial vendors currently do.

AUTHORIZATION LANGUAGE

Question: Last year we told you we weren't interested in dealing with authorizing language on the Labor-HHS Appropriations Bill. Your new budget, however, includes what appears to be authorization language designed to increase your revenue from Library users. Please explain to what extent would this language make the Library less competitive with the private sector--and turn a social institution into a business.

Answer: NLM currently receives funds in payment for certain services to the public and private sectors which are returned to the Treasury. The proposed appropriation language would return these funds, approximately $1.5 million projected for FY 1985, directly to the NLM appropriation to offset general operating costs of the Library rather than return them to the general treasury. The President's budget request does not offset these anticipated collections so an additional $1.5 million in revenues would be available to us if the language is adopted. If Congress approves this concept and we gain a certainty as to the amount of money received each year, future year budget requests might be offset by such sums. However, there are no plans to turn the Library into a business operation by making it dependent on the sale of its services. The proposal is simply one of using fees already collected to offset general operating costs.

## USE OF COMPUTERS

Question: The subcommittee is very interested in your use of computers for integrating information in a health center setting. One of your current projects has resulted in planning grants to five universities, including the Oregon Health Sciences University. What will these systems be used for?

Answer: The purpose of the IAIMS program is to aid health professionals in academic health science centers in obtaining information as efficiently as possible. Currently, a health professional must consult many different information sources to get information that he or she needs for patient care, research and teaching. The ultimate purpose of the IAIMS program is to develop methods to combine information sources such as patient records, research results, clinical protocols, disease registries, laboratory tests, academic records, and articles in medical books and journals into a single, efficient and easy to use system.

The first phase of NLM's Integrated Academic Information Management Systems (IAIMS) program is being accomplished through strategic planning contracts and grants. Four competitive contracts have been awarded to Columbia University, Georgetown University, the University of Maryland, and the University of Utah. In addition, at the direction of Congress, NLM has awarded a noncompetitive contract to the Oregon Health Sciences University (OHSU) for the development of a Biomedical Information Communications Center (BICC). NLM has also announced the availability of grant support for IAIMS activities.

The planning, development and implementation of a BICC at OHSU is a part of this IAIMS program. NLM has awarded the first of two planned contracts to OHSU for this purpose effective January 1, 1984. The purpose of the first contract is to engage in a comprehensive strategic planning process for the management of OHSU's information resources, both now and in the future, which will lead to an appropriate organizational and planning base for the successful operation of the BICC. The second contract will provide for the development and implementation of the BICC. The major components of the BICC will include a regional network to deliver information throughout the State of Oregon, an automated library support system for the OHSU library, and a research and development capability.

Question: It's our understanding that your budget for this work in Fiscal 1985 is about $1.3 million. Since you could be headed for experimentation and implementation phases, how much will you actually need?

Answer: There will be three phases to the IAIMS program. First NLM is making planning awards to develop strategic plans for the IAIMS. The development phase will enable the most promising plans to be tried out and experimented with. Finally, in the implementation phase, the actual implementation of four or five working systems will be supported. We will need to commit over the next 6-7 years about $12 million in federal funds.

It should be noted that NLM's expectation for the whole IAIMS program is that significant institutional cost-sharing will be involved, as evidenced by the four contracts awarded to Columbia University, Georgetown University, the University of Maryland, and the University of Utah, in which the universities are contributing about 70 percent of the total funding required for the planning effort.

Question: Tell us what you are doing with a project called "Medical Informatics." We understand it has something to do with medical risk assessment and may get into the area of artificial intelligence.

Answer: Medical Informatics is a program of research training, career development, and research support to increase to a critical mass the number of well trained young investigators who will explore fundamental problems in the organization, maintenance and delivery of biomedical knowledge. The basic issue for the Library is, as it has always been, to provide health practitioners with the information they need, when they need it and in a format that can be readily used. It is now possible to conceive of extending the great bibliographic data bases such as Index Medicus, which provide citations to articles that may contain the information needed, to knowledge bases which provide direct answers to the health practitioner's questions. To create such knowledge bases, and to update and maintain them, requires research into problems of knowledge representations. It is clear that the computer can manipulate numbers; add them, divide, subtract, multiply, substitute, etc. What is needed is a representation of information that permits similar manipulations. It will then be possible to create and maintain state of the art knowledge bases which truly provide "expert consultations" to assure that the best available information is applied to clinical decision making. Then the true benefits of the nation's biomedical research investment can be assured to be available at the bedside.

Question: How much are you budgeting for "Medical Informatics" and, in your professional judgment, what will you actually need?

Answer: In FY 1985, NLM expects to obligate $2.2 million dollars for its Medical Informatics program area. In the absence of any constraints due to limited resources, I believe the Library should now initiate a program of comprehensive centers of excellence in Medical Informatics. By the end of a phase-in period of four or five years, I think we should be supporting 12-14 centers, each costing approximately $800,000 annually. In each such center, NLM would support training of highly skilled career investigators, provide adequate core research funding, and support career development programs for experienced researchers.

## MEDICAL LIBRARY ASSISTANCE ACT AUTHORIZATION

Question: Statutory authority for the programs under the Medical Library Assistance Act expired at the end of Fiscal 1983 and the programs are being kept alive through the continuing resolution. What effect, if any, has this lapse in authorization had on the programs involved?

Answer: The stability of the MLAA programs has been affected by a series of single year spending authorities. Uncertainties regarding future years' funding capabilities have hindered research and development initiatives such as Medical Informatics and Integrated Academic Information Management Systems, and retarded progress in the enhancement of the national biomedical communications network through our Regional Medical Library program. Both the House and Senate have called for 3 year authorizations of approximately $10, $11, and $12 million.

## BIOETHICS SUPPORT

Question: In Fiscal 1984 we encouraged you to make available $300,000 for a bioethics library and information retrieval system. We understand you plan to contribute only $150,000 and that you were trying to round up additional funds from other Institutes. How much will go into this project in FY 1984 and what are your plans for FY 1985?

Answer: Since 1974 NLM has supported a Bioethics Information System by grants totalling nearly $900,000. In the FY 1984 budget process, the conference action increased the NLM budget by $150,000 for Bioethics. Subsequently, NLM reviewed, and has since funded as a Cooperative Agreement, a competitive proposal from Georgetown University's Kennedy Institute for Ethics for enhancing their Bioethics Information System. The total approved cost of the first year of this project exceeds $150,000; however, in consideration of the cross disciplinary interest in bioethical issues, ten other NIH institutes are contributing to the total initial award of $202,000. The three-year project includes $250,000 approved for FY 1985 and $221,000 for FY 1986.

Question: How does the Library function in terms of serving NIH and institutions with an interest in ethical issues in medicine?

Answer: The Library provides online access to the BIOETHICSLINE database. BIOETHICSLINE, produced by the Center for Bioethics, Kennedy Institute of Ethics at Georgetown University, contains citations to print and nonprint materials which discuss ethical questions arising in health care or biomedical research. The Library staff also provide reference service in response to individual requests for information on ethical issues and prepare and distribute literature searches on ethical topics of more general interest. In the past year literature searches on general topics such as in vitro fertilization, hospices, the homeless, and the relationship of mental disorders and violent crimes have been prepared.

## Questions Submitted by Senator Daniel K. Inouye

### HHS STUDY OF NLM

Question: Has the study by the Department of Health and Human Services of NLM's pricing policies been completed?

Answer: Yes, the final report was completed December 12, 1983.

Question: Was there a recommendation for differential pricing to domestic commercial and non-health related users?

Answer: The study recommended that the NLM Board of Regents reexamine the issue of differential pricing. At the same time, the study endorsed NLM's current pricing policy of recovering access costs, and rejected market-rate pricing as an across the board policy.

Question: What is the status of implementing the full cost differential pricing recommendations?

Answer: On March 26, the NLM Board of Regents Subcommittee on Pricing convened a public meeting to consider this issue and hear testimony from representatives of the public and private sectors. The Board of Regents will consider the issue at their next meeting on May 24.

### QUID PRO QUO AGREEMENTS

Question: Does the NLM lease the MEDLARS tapes and provide direct online access through "Quid Pro Quo" agreements with fourteen foreign countries and through private sector vendors for use of MEDLARS by foreign private entities?

Answer: Unfortunately, confusion has resulted from the term "quid pro quo." NLM's international bilateral agreements are with institutions designated by a country to serve as a national biomedical information resource. Actual payment for the leasing of MEDLARS tapes or online access to NLM is made directly to the National Technical Information Service (NTIS), an arm of the Department of Commerce. Through NTIS, tapes are also made available to domestic private sector vendors. The NLM pays the foreign centers for indexing done for us at the equivalent rate NLM pays domestic commercial contractors.

Question: Can you please tell us what was the total dollar value of services NLM received in FY '82 and FY '83 under the "Quid Pro Quo" agreements? For each country providing such services can you please tell us the dollar amount of services provided and the amount received by MEDLARS contractors under the "Quid Pro Quo" agreements?

Answer: In FY 1982 the total dollar value of services received by NLM under the bilateral agreements was $767,589 and in FY 1983, $881,392. The distribution by country was as follows:

| | FY 1982 | | FY 1983 | |
|---|---|---|---|---|
| Country | Indexing services done in the foreign center | Indexing and key-boarding done by U.S. contractors and paid for by the foreign ctr. | Indexing services done in the foreign center | Indexing and key-boarding done by U.S. contractors and paid for by the foreign ctr. |
| Australia | 0 | $47,739 | 0 | $111,375 |
| Canada | 0 | 194,461 | 0 | 196,869 |
| Colombia | 0 | 25,000 | 0 | 14,996 |
| France | $18,196 | 123,571 | $13,055 | 227,654 |
| Germany | 8,294 | 47,300 | 5,230 | 107,700 |
| Italy | 0 | 19,999 | 0 | 10,015 |
| Japan | 0 | 69,592 | 0 | 28,523 |
| Mexico | 0 | 40,912 | 0 | 0 |
| PAHO | 5,271 | 12,455 | 4,674 | 6,774 |
| So. Africa | 3,154 | 31,387 | 3,239 | 15,318 |
| Sweden | 13,347 | 19,997 | 11,663 | 75,648 |
| Switzerland | 0 | 31,667 | 0 | 0 |
| United Kingdom | 55,247 | 0 | 48,659 | 0 |
| Subtotal | $103,509 | $664,080 | $86,520 | $794,872 |

Total, FY 1982.......$767,589

Total, FY 1983..................................$881,392

Question: What percentage of the MEDLINE database is created under the "Quid Pro Quo" agreements through payments by the foreign partners to U.S. Contractors?

Answer: In FY 1983 27% of the citations indexed, 53% of the citations keyboarded and 25% of the abstracts keyboarded were done by U.S. contractors and paid for using monies from the bilateral agreements. An additional 9% of the indexing was performed by the foreign MEDLARS centers and credited to their accounts.

Question: Instead of bartering with the foreign partners for performance of these important services in creating MEDLINE, couldn't NLM pay the U.S. contractors itself to perform these services and direct the foreign "Quid Pro Quo" partners to pay the U.S. Treasury for use of the databases?

Answer: Yes, that is an alternative but beginning in FY 1984 governments are paying NTIS for their use of the MEDLARS databases. Invoices for the indexing, keyboarding of citations, and keyboarding of abstracts formerly paid directly by the foreign centers are now submitted to NTIS for payment. All excess funds will be returned to the U. S. Treasury.

## SALE OF MEDLARS TO FOREIGN USERS

Question: Does NLM charge the same fees under the "Quid Pro Quo" agreements for use of MEDLARS by private foreign entities, including foreign corporations which compete with U.S. corporations, as those charged U.S. users?

Answer: NLM has no direct contact with individual foreign users accessing MEDLARS databases through the foreign centers or U.S. commercial database vendors. NLM does not suggest or stipulate the fees charged individual foreign users by foreign governmental institutions that serve as centers or by U.S. commercial database vendors.

Question: Are the fees for foreign use set by NLM to recover the full cost of MEDLARS, including the full cost of creating the MEDLARS databases?

Answer: The fee for domestic commercial vendors and foreign governments to lease MEDLINE is a use fee of $4.00 per connect hour and $0.01 per citation printed offline with a annual minimum of $20,000. Revenues received resulted in the recovery of a little more than the full cost of creating and distributing our computer tapes.

Question: Does NLM believe that foreign private users of MEDLARS should be subsidized to the same extent as non-profit U.S. users?

Answer: NLM's international agreements are with an institution designated by another country to serve as a national biomedical information resource. The other countries' policies determine the pricing structure for their services.

Question: What consideration has been given to ending the NLM's subsidized pricing of MEDLARS to foreign private users?

Answer: NLM is reviewing the charges made for leasing and providing direct online access to its databases; however, these are charges made to institutions designated by foreign governments to provide MEDLARS database services. NLM does not determine the charges for services made to these institutions' users.

Question: Are foreign governments making a profit at U.S. taxpayer expense in selling MEDLARS access to local commercial companies or are U. S. taxpayers providing a subsidy that the foreign governments pass on to their private MEDLARS users through extremely low prices? Could you please tell us what fees are charged by each of the foreign "Quid Pro Quo" partners for resale of the MEDLARS databases?

Answer: NLM does not know the fees charged by each of the foreign governmental institutions for individual uses of the databases nor does it attempt to determine whether the services are provided at a profit or subsidized.

## SUBSETS OF MEDLINE DATABASE

Question: Did the NLM recently announce a new product namely discrete subsets of the MEDLINE database to be marketed on floppy disks and other computer-based formats?

Answer: NLM has received many requests from physicians, other individuals, and groups, asking that portions of the large MEDLINE database--known as "subsets"--be made available. With the proliferation of microcomputers, subsets of MEDLINE could be distributed and accessed directly on such equipment instead of through NLM's main computer facility. Subsets of MEDLINE represent a reformatting of an existing product to better meet the needs of the biomedical community. Recently, we announced a draft policy on the provision and pricing of subsets, and invited and received comments from all sectors of the community. As yet that policy has not been finalized and therefore subsets are not available at this time.

Question: Has the NLM considered potential competition with the private sector in creating, marketing and pricing this new product, particularly to commercial users?

Answer: The commercial sector is providing us comments on our draft subset policy, and we will consider their input in developing a final policy.

## OFFICE OF THE DIRECTOR AND BUILDINGS AND FACILITIES

### STATEMENT OF CALVIN B. BALDWIN, ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. EDWIN D. BECKER, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES

ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT HEALTH AND HUMAN SERVICES

### PREPARED STATEMENT

Senator WEICKER. Next we will hear from the Office of the Director of NIH. This also will include a discussion of the appropriation for buildings and facilities. The Office of the Director has authority for overall administration of NIH and for provision of central support services. Buildings and facilities concerns itself with the NIH physical plant, both here in Washington and at several out-of-town locations.

The budget request for the Director's Office is $27.5 million, an increase of $789,000 over the current fiscal year appropriation. For buildings and facilities, the request is $11 million, which is $13.9 million below the fiscal 1984 appropriation.

The principal witness for both appropriations is Calvin B. Baldwin, Jr., Associate Director for Administration at NIH.

[The statement follows:]

### STATEMENT OF CALVIN B. BALDWIN

I am pleased to have the opportunity to discuss with the committee the Office of the Director and the buildings and facilities appropriations of the NIH.

### OFFICE OF THE DIRECTOR

For reasons of efficiency and economy in operations, funds for the overall direction and administration of the National Institutes of Health, and for the centralized provision of a number of very essential support services are provided through the appropriation to the Office of the Director.

This appropriation funds those components of the central administration which are primarily responsible for the development of NIH-wide policy and procedures and the coordination of program activities. Chief among these offices is the Immediate Office of the Director, including the principal associates of the Director and staff officers who provide advice and assistance in the administration and coordination of the intramural and extramural research programs of the bureaus, institutes, and divisions.

Other offices provide leadership in such areas as equal opportunity, program planning and evaluation, disease prevention, medical applications of research, public and scientific communication, protection from research risks, management analysis and review, contracts and grant administration, and budget and personnel management. These offices are assisted in their efforts by numerous formal and informal advisory groups, both internal and external to the NIH, representing a wide array of viewpoints on issues central to the administration of biomedical research.

Mr. Chairman, the appropriation request for 1985 for the Office of the Director is $27,509,000, an increase of $173,000 over the 1984 level of $27,336,000.

### BUILDINGS AND FACILITIES

The second appropriation for which I am testifying is the buildings and facilities appropriation that provides funds for the design, construction, and repair and improvement of clinical and laboratory buildings and supporting facilities for the National Institutes of Health.

The appropriation request of $11,100,000 in fiscal year 1985 is for the following:

*Clinical center modernization.*—The clinical center, a 30-year old building, houses all the patient care and clinical research programs of the National Institutes of Health at Bethesda, as well as some of the basic research programs. In fiscal year 1985, we are requesting $6,900,000 to continue the modernization of this building. The modernization effort began in 1979 and is required to remove functional obsolescence and repair physical deterioration; to satisfy the latest code requirements for the handicapped, for environmental health, and for the safety of the patients and staff; and to integrate the activities in the clinical center with their operational counterparts in the new ambulatory care research facility. The program, involving more than 50 projects, is scheduled over a 10-year period so that clinical and basic research can remain operational during the entire modernization period.

*Repairs and improvements—Plant.*—We are requesting $1,620,000 to continue the program of major repairs and improvements to the various electrical, mechanical, and structural components of the physical plants at Bethesda, Poolesville, and Baltimore, MD; Hamilton, MT; Research Triangle Park, NC; Perrine, FL; and other field stations for which NIH is responsible. The physical plants are quite extensive and many of the buildings and supporting facilities have been in service for four decades. There is a recurring need to provide for the repair and upgrading of physical plants.

*Repairs and improvements—Program.*—A funding level of $2,580,000 is also requested to continue the financing of alterations directly related to program needs. The work includes changes in physical facilities to accommodate revisions and new initiatives in research efforts.

Thank you. I shall be happy to respond to any questions you may have.

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### BIOGRAPHY OF CALVIN B. BALDWIN, JR.

*Birthplace and date*: Radford, VA; December 22, 1925.

*Present position and title*: Associate Director for Administration, NIH.

*Education*:

June 1943: Bethesda-Chevy Chase High School, Bethesda, MD.
June 1949: University of North Carolina, Chapel Hill, NC—A.B.
1949–51: University of North Carolina, Chapel Hill, NC.
1952–53: American University, Washington, DC.
1960–61: Harvard University, Cambridge, MA—M.P.A.

*Experience*:

1980–Present: Associate Director for Administration, NIH.
1970–80: Executive Officer, National Cancer Institute, NIH.
1963–70: Executive Officer, National Institute of Child Health and Human Development, NIH.
1962–63: Assistant Chief, Grants Management Branch, Division of Research Grants, NIH.
1961–62: Executive Officer, Division of General Medical Sciences, NIH.
1958–61: Administrative Officer, Division of General Medical Sciences, NIH.
1957–58: Administrative Officer, Division of Research Services, NIH.

1955–57: Budget Examiner, Office of the Director, NIH.

1953–55: Organization and Methods Examiner, NIH, PHS, DHEW, Bethesda, MD.

Sept. 1952–Feb. 1953: Civil Service Intern, Federal Security Agency, Public Health Service, Washington, DC.

1951–53: Methods Examiner, Federal Security Agency, Public Health Service, Washington, DC.

1949–50: Research Assistant, Institute of Research in Social Science, Chapel Hill, NC.

*Military service*: 1944–46: Corporal, U.S. Army.

*Honors and other special recognition*: Phi Beta Kappa; W.A. Jump Meritorious Award, 1960; and DHEW Superior Service Award 1973.

### BUILDINGS AND FACILITIES BUDGET

Senator WEICKER. To start, could you tell us why you're proposing an almost $14 million cut in the buildings and facilities appropriation?

Mr. BALDWIN. Let me ask Dr. Becker, who is in charge of buildings and facilities, to answer that question, if I may.

Dr. BECKER. Mr. Chairman, the buildings and facilities budget varies considerably from year to year, depending on projects included. We have at present two major renovation projects underway at NIH. The first is the clinical center modernization project for which continuation funds are requested in 1985. The second is the renovation of the older laboratory buildings. Last year you provided funds for constructing the first of those buildings, building 8, and for designing the second one, building 4. We will need funds for constructing building 4, at some time in the future. The construction of building 8 will be completed late in fiscal 1985. We would not be in a position to use building 4 construction funds until the latter part of fiscal year 1985.

Senator WEICKER. Go ahead. Please proceed.

Mr. BALDWIN. Thank you, Senator Weicker. My testimony covers two appropriations that support all NIH programs. The appropriation for the Office of the Director includes the Director and his staff who assist him in the administration and coordination of NIH programs and administrative support functions, such as budgeting, accounting, and personnel.

The appropriations request for 1985 for the Office of the Director is $27,509,000, an increase of $173,000 over the 1984 level. This will maintain the Office of the Director at its current level.

The second appropriation for which I am testifying is the buildings and facilities appropriation that provides funds for the design, construction and repair, and improvement of NIH facilities. The major item of our request under this appropriation is $6,900,000 to continue the modernization of the clinical center. This building houses all of the patient care and clinical research programs of the NIH at Bethesda, as well as some basic research programs.

That's a brief summary, Senator Weicker. Dr. Becker and I will be glad to answer questions.

Senator WEICKER. I don't think I've got too many here.

One that relates to the convent. Has purchase been completed?

Mr. **Baldwin.** We have completed the purchase of the convent, and have established a committee, under the chairmanship of Dr. Becker, to address the best utilization of that building and the 11-acre site.

Senator **Weicker.** Is that something you feel can be long range?

Dr. **Becker.** We are considering both short- and long-term uses. Since the beginning of March, we have been using one room as a conference room. There are several others that will be available by June for use as conference rooms and will accommodate study sections. This is an interim use.

We believe that we will continue the use of the building for some conference activities, but we hope to make it a center for educational activity. Dr. Wyngaarden and others at NIH have been very concerned with the training of medical students in biomedical research, and we have a program under development which we think can be effectively centered in that building.

So as far as the site itself is concerned, we have no plans for other construction on that site at the present time, although a need could arise in the future.

Senator **Weicker.** Yes; I think it is important to point that out. When we bought the property, it was the time to buy, because it was up for sale and everybody understood, it was supposed to be used for the future. It was a valid request, and it will find its use.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I have some questions for response to the record. Otherwise, that should do it.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## Questions Submitted by the Subcommittee

### BUDGET SHORTCOMINGS

Question: You've already heard me go over the shortcomings of the fiscal 1985 NIH budget. To what degree were you consulted in the formulation of your budget -- or were you simply handed a number and told to find ways to live within it?

Answer: Formulation of the 1985 budget request followed an iterative process that led at each successive review level to a refinement of funding priorities. At each level, information was requested and provided as to the impact of various decisions on our operating programs. The competing needs were weighed and a request level was determined.

Question: What is the impact of the budget request on your office?

Answer: The budget request of the Office of the Director will maintain existing offices and programs at approximately the current level.

Question: How much additional funding above the budget would be required in fiscal 1985 to maintain your Institute at the same level of effort as in fiscal 1984.

Answer: Approximately $1,166,000 in additional funds would be needed in FY 1985 for the Office of the Director to maintain the same level of effort as FY 1984.

Question: The Budget proposes a staff cut of 588 for all of NIH. What is your share of this proposed reduction -- and where will you take it? With what effect on research?

Answer: The Office of the Director's share of the proposed staff reduction is 25 FTEs. The proposed reduction will be made in other than full-time permanent positions. We are currently studying the situation to determine the exact positions to be affected.

### NEW STAFF POSITIONS

Question: We note that Dr. Wyngaarden has made some major staff appointments. We have Deputy Directors for intramural research and for extramural research and training. We also have an overall Deputy Director. What led to these appointments and how will they improve the functioning of the NIH?

Answer: The establishment of these positions is intended to reflect more accurately the discrete responsibilities of the intramural and extramural research programs. The position of Deputy Director for Intramural Research was formerly entitled Deputy Director for Science. The position, Deputy Director for Extramural Research and Training, was formerly the Associate Director for Extramural Research and Training. The title changes recognize the importance of the two areas of concentration and establish comparable focal points in the Office of the Director for intramural and extramural research policy and administration.

Question: What problems are the appointments designed to overcome?

Answer: The Deputy Director for Intramural Research is the principal advisor to the Director on the substance of science and intramural research policies and will work with the Institutes in resolving policy problems and coordinating NIH intramural programs. The Deputy Director for Extramural Research and Training coordinates the development and implementation of policies affecting the extramural programs, and will maximize the value of NIH training programs. Neither of these position titles were designed as a response to a particular problem or set of problems, but rather as a measure of recognition of the importance of the intramural and extramural science programs.

## CONSENSUS DEVELOPMENT CONFERENCES

Question: Consensus development conferences are held by NIH to bring together expert opinion on disease treatments, procedures, or techniques of current interest to health professionals. What new consensus development conferences are being planned in Fiscal 1985?

Answer: The following conferences are planned:

| TOPIC | SPONSOR | DATE |
|---|---|---|
| Limb Sparing Treatment of Adult Soft Tissue and Osteogenic Sarcomas | NCI | December, 1984 |
| Treatment of High Blood Cholesterol | NHLBI | December, 1984 |
| Traveler's Diarrhea: Prophylaxis and Treatment | NIAID | January, 1985 |
| Health Implications of Obesity | NIADDK<br>NHLBI | February, 1985 |
| Diagnostic Screening for Lung Cancer | NCI | May, 1985 |
| Anesthesia in the Dentist's Office | NIDR | May, 1985 |
| Electroconvulsive Therapy in Psychiatry | NIMH | June, 1985 |

Question: How expensive is it, on average, to hold these conferences?

Answer: On the average, each conference costs approximately $65,000.

Question: To what extent do clinicians modify any of their practices in response to the findings of your consensus conferences?

Answer: The consensus statements are widely disseminated among clinicians and medical educators. Anecdotal evidence suggests a significant impact of these statements on physician behavior. The results of the Burn Care Conference were widely accepted by burn specialists and evidence suggests that cesarean section rates declined following the cesarean conference. The impact of the Consensus Development Conference Program is now under rigorous study by the Rand Corporation and results are expected in July, 1985.

## PURCHASE OF CONVENT

Question: Last Year Congress gave you $4.2 million for the purchase of an 11-acre parcel of land adjoining the Bethesda campus. The land included a convent owned by the Order of the Visitation. It's our understanding that the purchase has been completed and that a committee has been appointed to review how the new space will be used. What can you tell us?

Answer: A committee has been appointed to consider both short-term and long-term use of this building. The short-term plan is to use the facility for badly needed conference space. Our Division of Research Grants plans to use the rooms for Study Section meetings in the June and October rounds. At other times, these rooms will be available for general use. For the long-term, the primary purpose of the purchase was not to obtain the 60-year old convent building, but to acquire the eleven acres that form a natural part of the NIH campus. As for long-term use, the Committee has recommended several options. Among the proposals under consideration are uses formalizing the convent as a conference center or uses furthering the education and training of medical students in the research sciences. Depending on these proposals' ultimate refinement, they could result in the need for conference rooms, and possibly, a teaching laboratory. The building's current configuration lends itself to an adaptation of this type. We expect to make a decision on uses in the next few weeks.

Question: How will the new building reduce your need for off-campus rental property for other NIH activities?

Answer: The availability of the convent will not make a major impact on the use of off-campus rental space because of the short-term and long-term uses described above. Off-campus rental property is used primarily by administrative and scientific staff for office and laboratory or laboratory support purposes. The proposed use of the convent, as a science education and conference center is a new initiative for which the NIH has never had space available.

## BARRIERS TO THE HANDICAPPED

Question: In the current fiscal year, Congress included some funds for the removal of barriers to the handicapped at NIH. There initially was reference to $1 million, but this was modified by the conference on our bill. How much did you actually use on removal of barriers to the handicapped and what work was done?

Answer: Our FY 1984 program for the removal of barriers to the handicapped totals $940,000 in funds available. Several construction contracts are in various stages of implementation. These total $365,000 and are as follows:

| | |
|---|---|
| Renovation of rest rooms, Building 12A.......... | $ 35,000 |

| | |
|---|---|
| Exterior handrails for the handicapped, ACRF.... | 10,000 |
| Replacement of automatic doors for the handicapped, Building 10A.......................... | 20,000 |
| Installation of elevators for use by the handicapped, Building 13..................... | 300,000 |

An architectural and engineering firm with special knowledge of handicapped needs has been retained to develop an evaluation study and program to identify the projects necessary for compliance. The cost of this study is $35,000. Based on these findings a plan will be developed for the obligation of the remaining funds.

Question: What are your plans for Fiscal 1985 and how much money will you require?

Answer: At present there is no money in the FY 1985 budget for the removal of barriers to the handicapped. However, the results of the above study will generate design and construction projects for FY 1985 that will be funded by the available balance from FY 1984.

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## Questions Submitted by Senator William Proxmire

### BUILDINGS AND FACILITIES

Question: Last year, in a response for the record, you indicated that the unobligated and uncommitted balance in your buildings and facilities account at the end of fiscal year 1983 would be approximately $5,707,000. Your actual unobligated balance at the end of the year was $14,565,000. How much of this total was uncommitted?

Answer: Of the actual FY 1983 unobligated balance, a total of $11,876,000 remained uncommitted.

Question: Please explain any discrepancies between your estimated end-of-year uncommitted balance and your actual balance?

Answer: The difference between our estimated and actual end-of-year balances is $8,858,000. The discrepancy is directly related to the difficulty in scheduling construction and renovation work, given the operational realities of employee turnover, coordination of numerous contractors and architectural firms, and advertising and evaluating bids for awards. These factors have resulted in some slippage on the Clinical Center Modernization program and to a lesser extent on other projects in the appropriation all of which have led to the discrepancy noted.

Question: Last year you listed several reasons for "unobligated balances in the Buildings and Facilities account at the end of each fiscal year." This wording strongly implies that you consistently carry over significant unobligated balances, which is understandable. If this is indeed the case, why do your justifications show no unobligated balance at the end of fiscal year 1984?

Answer: The annual justifications are formatted to support and explain the President's request for the budget year. For comparison's sake, the document reflects the prior year actual and the current year estimate. This provides reviewers with the necessary chronology to assess the requested amount. The omission of unobligated balances in the current year from the document is not intended to mislead reviewers but rather to add clarity by providing a comparable figure for the budget year in question.

## SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow, when we meet again in this room to hear testimony of the administration's fiscal year 1985 budget request from the Secretary of Health and Human Services and also hear witnesses from the Centers of Disease Control, and Alcohol, Drug Abuse, and the Mental Health Administration.

Dr. Wyngaarden, I'd like to express my appreciation to you and to all the directors and their colleagues who presented testimony before this committee, and I want to assure you all of my admiration for the work that you do.

Once again, we will try our best in formulation of the budget to give the proper emphasis to this portion of the Nation's activity, an activity that I think it deserves. I think with all the hoop-la that we have to listen to, much of the efforts of you and your people go unnoticed and/or unappreciated, and I want you to know that the committee very much appreciates it and, indeed, I would say that our future as a nation lies more in your hands than some more publicized areas.

I would hope that when we are through with the formulation of the budget, that we will have something that meets with your approval and the approval of those that you work with.

I would also appreciate if, in the course of the next several weeks, you all would work very closely with my staff to make sure we're not just pushing money out there. And I think we can pick up a few extra dollars here and there that will cover the areas of priority, as you determine it, not as I determine it. I don't have that ability.

I thank you very much.

[Whereupon, at 11 a.m., Wednesday, April 4, the subcommittee was recessed, to reconvene at 9 a.m., Thursday, April 5.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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THURSDAY, APRIL 5, 1984

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Specter, Proxmire, Eagleton, and Chiles.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### OFFICE OF THE SECRETARY

**STATEMENT OF MARGARET M. HECKLER, SECRETARY**

**ACCOMPANIED BY:**

- JOHN J. O'SHAUGHNESSY, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
- ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET
- MARSHALL MANDELL, DEPUTY COMMISSIONER (SYSTEMS), SOCIAL SECURITY ADMINISTRATION
- PHILLIP N. HAWKES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT

### OPENING REMARKS

Senator WEICKER. The hearing will come to order.

Welcome, Madam Secretary.

Today we are glad to welcome the Secretary of Health and Human Services to our fiscal 1985 appropriations hearings. I recall, Madam Secretary, that when you took over HHS you told your new employees that the answer to the budget problem was not less compassion.

The past year has given you an opportunity to put that principle to work and in today's hearing we will have an opportunity to evaluate the effort.

Health and Human Services has a budget of more than $300 billion. Much of that budget covers the Social Security trust funds and does not fall within the purview of this subcommittee. Our jurisdiction extends to less than one-third of the HHS budget, but it covers a wide variety of sensitive health and welfare programs.

Our initial hearings which have taken place so far, Madam Secretary, with HHS agencies indicate that their fiscal 1985 budgets may have been put together either at OMB or in your office with little or no consultation with the various leaders within your agency. That is a matter that we will address later on.

## PREPARED STATEMENT

We are honored to have you with us. Please introduce your colleagues and then proceed with your opening statement.

[The statement follows:]

## STATEMENT OF MARGARET M. HECKLER

In the last two months --- since the official birth of the Administration's budget for fiscal year 1985, there has been intensive public and private analysis of the budget's impact on programs, policies -- and especially -- people. There have been numerous alternatives presented by members of the Senate and others to advance the debate on the pronounced fiscal problems which face the Federal government.

I come before you and your colleagues this morning prepared to discuss our programs, our policies and the dollar consequences on millions of American lives that the proposed $318.1 billion budget of the Department of Health and Human Services (HHS) will have.

Let me try to put a budget of this size into some kind of manageable perspective. Our proposed budget is $22 billion larger than that for fiscal year 1984. The entire Federal budget did not reach the $300 billion level until 1975. In 1985, HHS will spend more than $36 million an hour in benefits for more than 56 million Americans. Indirectly, it will touch and benefit nearly everyone.

The decrease in inflation has been a particular boon to my Department. Every time the inflation index increases by 1 percent, outlays for HHS rise by about $1.9 billion. This Administration's success in bringing down inflation has saved HHS -- and the American people -- billions of dollars for each and every year inflation has declined. In 1985 alone, we will spend $37 billion less than we would have spent if the 1981 inflation rate had continued unabated. Lower inflation means that every HHS dollar -- in benefits, in services, and in purchasing power -- is worth more to those who receive our assistance.

To further strengthen the integrity of our programs and the people they serve, we have worked to restrain our spending growth and to reform programs. Our budget increase for 1985 will be 7.3 percent, a significant decrease from the 17.7 percent increase in 1981. We have reduced that growth rate despite the fact that we serve more beneficiaries each year.

Of the Department's total budget of $318.1 billion, $77.5 billion consists of appropriations which are under the jurisdiction of this Subcommittee. I will emphasize this appropriations request in the remainder of my remarks.

## PUBLIC HEALTH SERVICE

For the programs of the Public Health Service (PHS) within this Subcommittee's purview, we are requesting $7.2 billion for 1985 reflecting this Administration's continuous commitment to sustaining and enhancing our premier national health research capacity; encouraging healthy lifestyles and continuing support of traditional disease prevention and control efforts; and assisting States in delivering health services through block grants.

### HEALTH RESOURCES AND SERVICES ADMINISTRATION

A total of $272 million is requested for activities of the Health Resources and Services Administration (HRSA).

This request for HRSA excludes funds for an expanded Primary Care Block Grant and the Maternal and Child Health Block Grant which are reflected in the Office of the Assistant Secretary for Health (OASH) budget request. This consolidation of block grants into OASH will help reduce Federal administrative costs and provide States with a single focal point in the Federal government for administrative matters regarding these grants.

Highlights of the 1985 HRSA budget include:

- National Health Service Corps (NHSC)

  The $67 million request for the NHSC will support a total field strength of 3,583 physicians and other health professionals, including 1,150 Federally salaried assignees in 1985. By increasing the opportunities to fulfill NHSC scholarship service obligations in health manpower shortage areas through private practice instead of Federal salary support, we will be able to increase the total NHSC field strength by 600 while permitting a decrease in Federal funding.

- Health Professions Education

  The 1985 budget request includes $100 million to support the training of health professionals. These funds, which include an additional $6 million for the Disadvantaged Assistance program and $5 million for special loan assistance, will be targeted principally to maximizing the opportunities for minorities and the economically disadvantaged to enter health professions careers. Funds are also requested to support special initiatives in those areas of health care education in which Federal assistance is likely to have the greatest impact.

  In addition to the budget authority requested for 1985, approximately $67 million will be available for student loans from the revolving funds at 1,645 health professions and nursing schools. These repaid loan monies, coupled with our significantly improved debt collection efforts, will enable schools to continue providing assistance to needy students.

- Health Planning

  No funds are requested for Health Planning in 1985, since its legislation has expired. If new legislation agreeable to the Administration is enacted, an appropriate budget request will be considered at that time.

CENTERS FOR DISEASE CONTROL (CDC)

The 1985 budget request of $280 million for CDC continues to emphasize health promotion and disease prevention in order to help control health care costs, reduce human suffering, and improve the Nation's health status. Excluded from this total is $89 million for the Preventive Health Services Block Grant which is budgeted under the Office of the Assistant Secretary for Health appropriation.

- Immunization

  Through CDC's leadership and financial assistance to States for immunization activities, many childhood diseases have been brought almost entirely under control. Immunization levels have reached new highs of over 96 percent, and cases of measles, mumps, rubella, tetanus, and polio have reached all-time lows. For example, the number of reported cases of measles in all of 1983 dropped to only 1,436 nationwide, a further 16 percent reduction from the previous record low reported in the prior year and a 97 percent reduction from the 57,345 cases reported just six years ago in 1977.

In 1985, $46 million, an increase of $4 million over 1984, is requested to maintain these record achievements and continue the development of the vaccine stockpile begun in 1983.

In addition, we are launching a new campaign to hasten the elimination of rubella, or "German measles." Rubella in pregnant women has been a primary cause of deafness in children; thus, this priority of the Department has important long-term benefits. There were about 1,000 cases of rubella reported in the United States in 1983, with many occurring in adolescents and young adults, and our goal is to accelerate the eradication of this disease to protect future generations.

- Acquired Immune Deficiency Syndrome (AIDS)
Our number one public health priority continues to be the vigorous pursuit of the cause of AIDS and the development of effective prevention and treatment methods for this disease. Approximately $54 million in total Departmental resources (including $12 million in CDC) is requested in 1985 for AIDS research and investigations, an increase of $6 million over 1984 and $25 million more than the amount available in 1983. Total AIDS funding over this three-year period exceeds $130 million. Recent exceptionally promising research on AIDS indicates that a retrovirus may be implicated as a causative agent, though this will require considerable additional work to verify. However, we are very excited and feel like this may be the time that we can expect some encouragement from our efforts.

NATIONAL INSTITUTES OF HEALTH

The 1985 request for the National Institutes of Health (NIH) includes $4.6 billion, an increase of $89 million above 1984 and $541 million above 1983. This budget will continue our leadership in biomedical and behavioral research, leadership which is vital to ensure long-term improvements to our Nation's health.

- In 1985, $2.5 billion is requested to fund 5,000 new and competing research project grants and nearly 12,100 continuation grants. This is the second year in a row that we will exceed 17,000 grants, a record high number of projects. The research grant mechanism remains our highest priority in view of the important contributions made to the advancement of biomedical research through this investigator-initiated mode of research.

  The budget request is sufficient to provide a 5 percent increase over 1984 in the average research project grant award as well as provide for full indirect costs, though the Administration remains concerned about rapid increases in indirect costs.

- $164 million is requested to support 9,000 research trainees, including a 5 percent stipend increase.

- All other research mechanisms, such as research centers, contracts, disease control awards, and intramural research, are maintained in 1985 at essentially the 1984 level of $1.8 billion.

The Federal investment in biomedical research, which has more than doubled since 1975, continues to pay off in dramatic fashion. In a recent major breakthrough, grantees supported by

NIH have located the specific gene for Huntington's Disease. This represents a major step toward detecting carriers of Huntington's prior to its manifestation. This discovery is also significant because it demonstrates how the techniques of basic molecular biology can be used to attack a disease whose biochemistry is completely unknown and for which there is no cure.

Important progress in cancer research is continuing, and the survival rate for those with cancer is now thought to be at least 50 percent. Cancer deaths among children were reduced by half in the period 1965-1979, and more gains are expected.

## ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

A total of $421 million is requested in 1985 for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the Nation's primary source of basic biomedical and behavioral research funding in the mental health and substance abuse fields. Excluded from this total is $472 million for the Alcohol, Drug Abuse and Mental Health Block Grant which is included in the appropriation for the Office of the Assistant Secretary for Health.

Similar to NIH, priority in ADAMHA will be placed on funding 500 new and competing research project grants, 702 noncompeting continuation grants, and 982 research trainees. Emphasis will be placed on basic biomedical research and addressing the major problem areas of schizophrenia, the most heavily abused drugs, the biological aspects of alcoholism, and teenage drunk driving which accounts for over 10,000 young lives lost each year in alcohol-related traffic accidents.

- St. Elizabeths Hospital

  In 1985, the Federal subsidy to St. Elizabeths Hospital will be $49 million, $21 million less than 1984, reflecting the third year of a planned ten-year phase-down of the direct Federal subsidy for the care of District residents who represent about 90 percent of the hospital's patients. The budget assumes that this decrease will be offset primarily by increased payments from the District of Columbia. We intend to continue discussions with the Congress, the District, and others on the future of the hospital, and we have submitted legislation to convert the hospital to a corporation in 1985.

## OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The 1985 request is $112 million for the programs in the Office of the Assistant Secretary for Health, and $1.5 billion for Health Block Grants.

- Health Block Grants

  The Administration remains committed to giving State and local governments greater control over the use of Federal resources to better meet the public health needs of their citizens, especially the economically disadvantaged.

  Funding for the Health Block Grants in 1985 will be increased by $32 million over 1984. Our request includes $89 million for Preventive Health; $472 million for Alcohol, Drug Abuse and Mental Health; $407 million for Maternal and Child Health; and $534 million for Primary Care. The latter amount includes $189 million for three programs (Black Lung Clinics, Family Planning, and Migrant Health) for which we will propose legislation to include as part of the Primary Care block grant. This consolidation will allow the States maximum flexibility to integrate these programs into a comprehensive primary care health service system, as well as streamline both Federal and State administrative costs.

- **Other OASH**

  Other OASH priorities in this budget include:

  -- $60 million for the National Centers for Health Services Research and Statistics,

  -- $15 million for the Adolescent Family Life Program to support 88 grants and contracts, and

  -- $7 million for Health Promotion and Smoking and Health activities.

## HEALTH CARE FINANCING ADMINISTRATION

The total 1985 HCFA budget request for Medicare, Medicaid and related programs includes outlays of $92.0 billion, an increase of $10.5 billion, or 13 percent, over the current estimate for 1984. This increase is due to the continuing rise in health care costs and to the projected increase in both the number of beneficiaries and the amount of services they use. Approximately 50 million beneficiaries will be served through the Medicare and Medicaid programs in 1985.

This budget reflects the Administration's continued commitment to constrain rising Federal health care expenditures. Although health care inflation has declined in the past few years, these costs are still growing about two times as fast as the general inflation rate. To moderate these cost increases and to encourage cost conscious behavior, the budget request includes a number of legislative proposals introduced to the Congress last year. Some of these proposals are included in bills pending before the House and Senate. Enactment of these proposals is an important step in our continuing efforts to slow the rapid rise in Federal health costs which, if not checked, will hasten the insolvency of the Medicare trust fund in future years.

For HCFA programs which require appropriations action, primarily Medicaid and a portion of the Medicare program, we are requesting $41.6 billion in 1985.

## MEDICAID

Medicaid appropriations of $21.6 billion are projected for 1985, $0.5 billion more than 1984. This request includes the impact of proposed legislative savings of $1.1 billion.

These legislative proposals are designed to stimulate more cost-conscious behavior on the part of beneficiaries, maintain incentives for States to moderate program growth, and improve the efficiency of program operations. Among the specific 1985 legislative changes are proposals to require nominal cost-sharing by program recipients and to maintain reductions in the Federal share of Medicaid.

## PAYMENTS TO HEALTH CARE TRUST FUNDS

A total of $19.9 billion is requested for the Payments to the Health Care Trust Funds appropriation, an increase of $2.2 billion above 1984. This account reflects certain general revenue payments to Medicare, the largest being the Federal share of premiums for individuals enrolled in the Medicare Supplementary Medical Insurance (SMI) program (Medicare Part B). The growth in the Federal payment for the Part B program is primarily a result of rising program costs and the need to keep the program actuarially sound.

PROGRAM MANAGEMENT

The 1985 budget request includes $96 million in appropriations and $1,131 million in trust fund transfer authority to administer the Medicare and Medicaid programs. Highlights of the program management appropriation include:

- Medicare Contractors
  A total of $918 million is requested, an increase of $56 million (6 percent) above 1984, reflecting our commitment to improve administration of Medicare. Approximately 80 percent of the budget request, or $737 million, is allocated to claims-processing services, while the remainder of the request finances payment safeguard activities (audits and medical/utilization reviews) and productivity investments which will improve the efficiency of claims payment operations.

- State Certification (Medicare)
  The 1985 budget request of $50 million, a 26 percent increase above 1984, supports survey coverage of approximately 67 percent of facilities participating in Medicare. This level will provide annual inspections of all skilled nursing facilities and hospices, and reflects the Department's strong commitment to protect the health and safety of Medicare beneficiaries.

- Professional Standards Review Organizations (PSROs) and Peer Review Organizations (PROs)
  The Tax Equity and Fiscal Responsibility Act of 1982 replaced the PSRO program with the PRO program. The 1985 budget request reflects phasing out all PSROs in 1984 and replacing their functions with PROs which will be responsible for determining the medical necessity,

appropriateness, and quality of health services delivered to Medicare beneficiaries. Unlike funding for the PSRO program, all costs for the PRO program ($171 million in 1985) will be charged directly to the Medicare Hospital Insurance Trust Fund. Therefore, no annually appropriated funds are required in this program area.

## SOCIAL SECURITY ADMINISTRATION

The fiscal year 1985 budget for the Social Security Administration's (SSA) income security programs for the aged, disabled and poor totals $211.7 billion in outlays financed through both trust funds and general fund appropriations. These programs, which constitute about 67 percent of HHS budget outlays, will provide benefits to almost 50 million people in FY 1985.

For programs subject to appropriations, we are requesting $23.0 billion as follows:

### SUPPLEMENTAL SECURITY INCOME:

The 1985 appropriations request for the Supplemental Security Income (SSI) program is $9.3 billion, plus an advance appropriation of $2.3 billion for the first quarter of FY 1986. Federal benefit payments under this program will provide assistance to an average of 3.7 million recipients each month.

The 1985 budget request reflects one more benefit payment in the budget year (12, compared to 11 in 1984). In addition, the budget includes a cost-of-living increase of 4.3 percent and a projected increase in the blind and disabled population.

## AID TO FAMILIES WITH DEPENDENT CHILDREN

A total of $6.7 billion is requested in 1985 for the Assistance Payments (AFDC) appropriation. These funds will provide assistance to an average of 3.6 million families each month.

The request includes several legislative initiatives, originally introduced as part of the 1984 budget, which build upon the reforms enacted in the Omnibus Budget Reconciliation Act of 1981 and the Tax Equity and Fiscal Responsibility Act of 1982. These proposals are intended to further ensure that assistance is provided only to those who are most in need and who are not in a position to provide for themselves, and that strong work requirements exist for all able-bodied applicants and recipients. In 1985, this legislation is estimated to save $633 million in AFDC and an additional $230 million in the Medicaid program, savings which are assumed in our request.

## CHILD SUPPORT ENFORCEMENT

Improvements in the Child Support Enforcement (CSE) program continue to be an important priority for the Administration. The 1985 appropriations request for CSE is $585 million, including savings associated with pending legislation which will lead to more effective State programs and higher collections from absent parents. Through 1984, we estimate that child support collections will have increased by nearly 50 percent since 1980, from $1.5 billion to $2.2 billion.

## LOW INCOME HOME ENERGY ASSISTANCE

For 1985, the Administration is proposing legislation which will significantly change the source of financing for this program. Under this proposal, the Low Income Home Energy

Assistance Program (LIHEAP) would receive an appropriation of $1,875 million to be derived from a newly established "Petroleum Overcharge Restitution Fund."

This fund would consist of revenues from existing oil escrow accounts in the Department of Energy and future oil overcharge litigation settlements. In addition, the legislation would authorize general revenue appropriations into the fund to ensure that sufficient resources are available to support LIHEAP at the $1,875 million level.

The Administration's legislation will not propose any change to the existing State allocation formula for this program.

## REFUGEE AND ENTRANT ASSISTANCE PROGRAM

The request for Refugee and Entrant programs totals $360 million in 1985, a decrease of $155 million below the 1984 level. This reduction reflects an anticipated decline of 74,000 in the average monthly number of refugees who are eligible for cash and medical assistance compared to 1984, and a parallel reduction in the need for targeted assistance after three consecutive years of declining refugee admissions.

## OTHER PROGRAMS

We are also requesting $1.3 billion for benefit payments to disabled coal miners with "black lung" disease, and $0.5 billion for Payments to Social Security Trust Funds, primarily for certain pre-1957 military service credits.

## LIMITATION ON ADMINISTRATIVE EXPENSES

The Limitation on Administrative Expenses appropriation provides resources for SSA to administer the Old Age and Survivors and Disability Insurance programs, the Supplemental Security Income program, and certain health insurance functions.

For 1985, we are requesting authority to spend $3.7 billion, a decrease of $48 million compared to 1984. This reduction is associated with procedural changes and systems improvements to further automate claims processing, case control, and other functions previously done manually. These changes are estimated to save 2,180 full-time equivalents (FTE) in 1985.

## OFFICE OF HUMAN DEVELOPMENT SERVICES AND OFFICE OF COMMUNITY SERVICES

We are requesting $5.4 billion in appropriations for programs administered by these offices in 1985.

The budget continues the policies of this Administration to support social services and related programs which promote self-sufficiency among program recipients, while focusing Federal resources on the most effective and efficient programs.

### BLOCK GRANTS

The 1985 budget request for the Social Services Block Grant is at the authorization level of $2.7 billion. No funding is requested for the Community Services Block Grant. Instead, the Department proposes that States use other sources of funding, including the Social Services Block Grant, to support those Community Services activities which are of the highest priority and most effective.

### HEAD START

A total of $1,075 million is requested for the Head Start program which provides comprehensive support services and early childhood development for poor and handicapped children up to age 5. This level will support services to nearly 430,000 children, the same number as in 1984, and an increase of approximately 55,000 over 1980. Of the total enrollment, at least 10 percent will be handicapped.

AGING PROGRAMS

The 1985 budget includes a total of $773 million for Aging programs, including the nutrition program of congregate and home-delivered meals and the Elderly Feeding Program which is proposed for transfer to HHS from the Department of Agriculture.

Within this total, $761 million is requested for Title III activities, about the same level as provided in 1984. In order to increase State flexibility in the use of these funds, the Department is proposing legislation to consolidate funding for State-operated programs into a single grant. Under this proposal, States will be permitted without restriction to allocate funds for services according to local priorities and need.

The budget request also provides $7.5 million for grants to Indian Tribes. This represents an increase of $1.8 million over the 1984 level and will enable approximately 27 additional Indian Tribes to develop service programs for their elderly members.

DEVELOPMENTAL DISABILITIES

A total of $64 million, an increase of $2 million over 1984, is requested for activities to develop and expand services for persons with developmental disabilities. In 1985, these funds will provide continued support for the Administration's effort to increase private sector employment opportunities for developmentally disabled individuals.

## FAMILY SOCIAL SERVICES

The 1985 budget requests a total of $642 million for programs to keep families together or to support other appropriate living arrangements when reunification of children and families is not possible. This amount includes $460 million for Foster Care, $169 million for Child Welfare Services and Training, and $13 million for Adoption Assistance.

## WORK INCENTIVES

In 1985, no funds are requested for the Work Incentives (WIN) program because, as studies by the General Accounting Office have demonstrated, this program has not proven to be cost-effective. Instead, legislation is proposed requiring alternative work experience programs under the AFDC program.

## DEPARTMENTAL MANAGEMENT

The budget includes $217 million for activities under the Departmental Management heading, $26 million below the comparable 1984 amount. Departmental Management activities include the Office of the Secretary, the Office of Inspector General, the Office for Civil Rights and the Policy Research program.

For FY 1985, our request includes staffing reductions for the Office of the Secretary based on initial recommendations of the Grace Commission. A significant portion of these reductions has already been met by transfers to the Department's Operating Divisions and by not filling vacated positions over the past several months.

We are continuing the current services level in our Office of Inspector General. Rooting out fraud, abuse and waste in the

Department's programs and activities will continue to be a top priority in FY 1985.

## MANAGEMENT ACTIONS

I also want to highlight the strong management actions we are taking to assure that our dollars serve as many people as possible. This, too, is part of caring, and we have attacked fraud, waste, and abuse aggressively. Last year, we ranked first in hotline calls received from citizens who wanted to blow the whistle on perceived wrongdoers. But we didn't simply take the calls; our Inspector General increased felony convictions by 700 percent (808 cases) over 1981.

I can also report steps which have resulted in specific gains to reduce costs and improve efficiency. We collected $2.7 billion in debt owed to us in 1982 and 1983, and expect to collect another $3.1 billion in 1984 and 1985. The Social Security Administration is improving its computer systems to better serve the public; we are consolidating several overhead functions with savings in staff; and we are reducing the paperwork burden on the private sector -- by 32 million hours since 1981.

This is the first budget that I have wholly presided over as Secretary of Health and Human Services. It is a renewal of my commitment to be a catalyst for caring and to be fiscally responsible to the American taxpayer.

That concludes my remarks, Mr. Chairman, and I would be happy to answer your questions at this time.

## SECRETARY'S INTRODUCTORY REMARKS

Secretary HECKLER. Thank you so much, Mr. Chairman.

As you know from your earlier hearings this week, we have made some very important breakthroughs, especially at NIH, in the area of cancer prevention. While it is not a subject of my formal presentation today I want to highlight the remarks of our very, very eminent Director of the National Cancer Institute outlining the changes in personal lifestyle which can help all Americans reduce their risk of cancer by approximately 80 percent and is one of the great health breakthroughs in our lives.

What this committee seeks to do, and what I seek to do as Secretary of the Department of Health and Human Services is to share these breakthroughs and incorporate them into our lives. Obviously, one of the key elements in reducing the risk of cancer is the adoption of dietary changes in our personal lifestyles. That cancer risk can be reduced by 35 percent if we change our diet, by increasing fiber content of food by 50 percent and reducing fat content by 25 percent.

Mr. Chairman, I thought a good time to begin would be today, and so as a symbol of my commitment to at least the tremendous increase in fiber, I wanted to share with you some bran muffins. And I really wish that we had Senator Andrews' wife's recipe and his great flour.

Senator ANDREWS. I'll send some to you.

Secretary HECKLER. I hope so. We tried to call you last night to get it.

However, this is a good way to begin.

[Bran muffins passed around.]

[Laughter.]

Secretary HECKLER. Mr. Chairman and committee members, 1 year ago I became Secretary of Health and Human Services. At that time I said that I wanted to be a catalyst for caring, someone who could galvanize the public and private resources of the country to meet human needs.

During my first year as Secretary I have tried to do that.

The efforts undertaken on behalf of the homeless are an example of this spirit. Under the direction of the Federal task force on the homeless, which I initiated and which President Reagan asked me to chair, and in conjunction with many private and public organizations, the Washington shelter was opened on January 15 of this year. When there were difficulties in the negotiations with the District of Columbia, we were very grateful to have the valuable support of Senator Specter in that regard. The success of the DC shelter, the largest shelter in the country, did not just happen. This administration and citizens concerned about the homeless have joined hands in communities and cities across the Nation to provide food and facilities to meet urgent needs.

In the 5-month history of the task force we have embarked on 40 such programs.

The role of the Federal Government is that of agent to facilitate the creation and support of shelters and to link food networks with the shelters. I contacted every member of the Cabinet and 13 Federal agencies and found their support was forthcoming and very, very helpful. When the Washington shelter needed beds and blankets to provide just basic comfort for the homeless, the Secretary of Defense provided 500 beds and the Secretary of the Army provided 1,000 blankets on very short notice, something like 24 hours notice.

The government can initiate and support such efforts and can cut through the redtape and open doors. But it was the individual Americans, church groups, citizen groups, who really made the difference. The support of America's less fortunate is now and should always be a joint cooperative effort.

In the health area we put new emphasis on the serious health threat presented by acquired immune deficiency syndrome, better known as AIDS, and by Alzheimer's disease, and we found new resources to finance greater research into these two specific areas.

We have successfully pushed for a new emphasis on preventive health care programs and have significantly increased our efforts. I believe that preventive health care will not only reduce some serious life-threatening diseases by perhaps half—and even the bran muffins will help in that regard—but will at the same time save billions of dollars in health care costs for Americans and for our country.

Our new prospective payment system is truly innovative. Under PPS we tell a hospital beforehand what the Government will pay or how it will reimburse for certain treatments, procedures, and other medical activities. It is a sensible approach that should have been taken long ago. I have worked many, many hours this year, hundreds of hours, I would say, to ensure the successful adoption and implementation of prospective payment. We have constantly reviewed our regulations and have sought in a very effective way to address the problems as they have arisen in this particular area.

We have tried to bring the same spirit of innovation to the area of social problems. For example, the problem of child support payments. This is one of my major priorities. The new incentive program we have developed is intended to sharply increase child support payments throughout the country, and by doing so to improve living conditions for many poor women and children. It is a creative way of ensuring compliance with the law and helping the poor without having to increase the budget. We thank the Senate Finance Committee for its action on our legislation and hope that the legislation will be finally passed by the Congress and signed into law very shortly.

Now I want to turn to the budget for fiscal year 1985 which will directly or indirectly affect almost every American family.

Although we are discussing this budget in dollar terms, my colleagues and I in this administration are mindful of the fact that we serve very, very fragile Americans. We have tried to be fair and responsive to their needs in this budget. At the same time we have not forgotten our responsibilities to the taxpayers of this country who make it possible for this Department to spend $318.1 billion this year.

The total outlay figure of $318.1 billion is truly a huge sum of money. It is $22 billion more than HHS spent in fiscal year 1984. The entire Federal budget did not reach $300 billion until 1975, and here we are 9 years later with $318 billion in one department.

HHS will spend more than $36 million every hour during a 24-hour day in benefits for more than 56 million Americans. No State, no community, no neighborhood is untouched by this budget.

As large as the budget request is, it would have been larger but for the administration's remarkable success in reducing inflation. Every time inflation increases 1 percent, outlays for HHS rise by about $1.9 billion, and this means that the dramatically lower inflation under this administration has saved taxpayers billions of dollars. In 1985 alone we will spend $37 billion less than we would have spent if the 1981 inflation rate had continued unabated. This would have translated into an additional $4 million per hour, 24 hours a day, for HHS under the earlier inflation rate, and that would not have purchased any health research, any meals for the elderly, health care services, or served any other programs in the Department. Lower inflation means that every HHS dollar in benefits, in services, and in purchasing power is worth more to those who receive our assistance.

In this budget we have worked to restrain spending growth while strengthening the integrity of our programs. Our budget increase for 1985 will be 7.3 percent, a significant reduction from the 17.7-percent growth rate we saw in 1981. We have reduced the growth rate despite the fact that we serve more beneficiaries every year.

## ENTITLEMENT PROGRAMS

The total HHS budget consists of authority to spend income from the Social Security and medicare trust funds as well as from our regular appropriations requests. For the Department's programs considered by this subcommittee our appropriations request for 1984 is $77.5 billion.

Entitlement programs make up most of this budget. HHS will spend nearly 96 percent of its outlays on these bedrock programs mandated by our national law, programs that are lifelines to our Nation's elderly population.

We are proposing some reforms in these entitlement programs. These reforms, along with some suggested changes in the tax law, will reduce the overall Federal deficit by $4 billion in 1985 and by more than $41 billion over the next 5 years. These kinds of reforms will help us to hold down spending even as more Americans are served by HHS—700,000 more elderly beneficiaries will be on the rolls in 1985 alone.

The elderly, of course, are one of the most important constituencies of this Department, and they are well served by this budget. It protects them and the dignity and independence they have earned. They now have a Social Security system restored to sound financial footing, for which I do congratulate you and the other members of the Congress. Because of this we are able to provide the full scheduled cost-of-living increase in benefits. Today I will join with Secretaries Regan and

Donovan to sign the annual trustees report which reiterates the financial soundness of the system put in place by the Social Security Amendments of 1983.

For medicare, as I stated earlier, we have taken an important step forward with the cooperation of the Congress by implementing the prospective payment system. It is a system which will reward efficiency and discourage wasteful practices while preserving the quality of health care. It is clear, however, that the prospective payment system itself is not enough to deal with the ballooning costs of our health entitlements.

Medicare and medicaid continue to grow rapidly, at a rate of almost 15 percent this year for medicare and 9 percent a year for medicaid. Without further reforms these two programs are expected to spend nearly $94 billion, 29 percent of HHS outlays, in 1985. The combined cost of these programs has escalated from $20 billion in 1975 to $46 billion in 1980 and has more than doubled since then. These are two very important programs.

The health entitlement programs which require appropriations action by this subcommittee are medicaid and a portion of medicare. We are requesting $41.5 billion in 1985 for this purpose.

Of the $41.5 billion, $21.6 billion is requested for medicaid. The request is based on November 1983 State estimates and includes the impact of proposed legislative savings of $1.1 billion. These legislative changes principally include proposals to require nominal cost sharing by medicaid recipients and proposals to maintain the reductions in the Federal share of medicaid enacted by Congress in 1981.

The remaining $19.9 billion is requested for payments to the health care trust funds appropriation, an increase of $2.2 billion over 1984. This account provides for certain general revenue payments for medicare, the largest being the Federal share of premiums for individuals enrolled in the Supplementary Medical Insurance Program.

Mr. Chairman, we are also proposing significant appropriations for our nonhealth entitlement programs. We are continuing our efforts to refocus the aid to families with dependent children to serve the neediest families. Our appropriations request of $6.7 billion includes a number of legislative proposals to strengthen work requirements and opportunities and to target resources to those most in need.

We are requesting $585 million for the Child Support Enforcement Program. Our legislative changes will give States new incentives based on performance and will influence how much the States collect based on how well they do it.

## DISCRETIONARY PROGRAMS

The 1985 budget maintains or increases funding for key discretionary programs. The request for the Public Health Service programs within this subcommittee's jurisdiction is $7.2 billion. This reflects a commitment to achieve better health for Americans by sustaining a strong national health research capability, continuing to encourage health promotion and disease prevention for the Nation, and assisting the States in the delivery of health services through block grant funding.

The request for the NIH totals $4.6 billion, an increase of $89 million over the 1984 appropriation and $541 million more than 1983. Our 1985 request will support 5,000 new and competing research project grants for a total of more than 17,000 projects.

The Federal investment in biomedical research, which has more than doubled since 1975, continues to pay off in dramatic fashion.

In a major breakthrough, which you heard about earlier this week from NIH witnesses, grantees supported by NIH have located the specific gene for Huntington's disease. This represents a major step toward detecting carriers of Huntington's prior to its manifestation. This discovery is also significant because it demonstrates how the techniques of basic molecular biology can be used to attack a disease whose biochemistry is completely unknown and for which there is no known cure.

Important progress in cancer research is continuing, and the survival rate for those suffering from cancer is now assessed to be at least 50 percent. Cancer deaths among children were reduced by one-half in the period 1965 to 1979, and more gains are expected.

We have undertaken a campaign which we intend to pursue with an arsenal of medical facts to attempt to persuade Americans to follow healthier lifestyles. On March 6 I announced a cancer prevention awareness campaign aimed at preventing 95,000 cancer deaths by the year 2000, including 75,000 through reduced smoking and 20,000 through improved diet, including more fiber, such as that which you shared this morning, and lower fat content. This offers such a great hope for reduction of cancer among Americans.

While the factors involved in cancer are numerous, tobacco and diet are at the top of the list. The most important causes of cancer are ones which we can control or influence, and we are going to make sure that the American public is made aware of this.

Among the most tragic of our health care problems are still drug abuse and alcoholism among young Americans. At HHS we have increased our research funding for these programs by 14 percent over 1984, and we will continue to support and encourage the movement among young people themselves to discourage drug and alcohol addiction and to help those who suffer from it.

Another important PHS priority is immunization. We have increased our funding for immunization programs in 1985 to $46 million. Immunization levels are at an all-time high of 96 percent or better, and the number of cases of childhood diseases which can be prevented by immunization are at record lows. For example, in 1983 there were only eight reported cases of polio in the United States and an all-time record low number of diptheria cases. Indigenous measles is virtually nonexistent in our country, and this is obviously not the case in other parts of the world.

Finally, for PHS we are requesting $1.5 billion for health block grants in 1985. I believe that these block grants, which allow States to fund their highest health service priorities, have been very successful since their implementation in 1982.

We are requesting $5.4 billion for important discretionary programs in the Office of Human Development Services. For the Head Start Program we are requesting $1.075 billion to maintain enrollment at 430,000 students in 1985, the same level as in 1984, and an increase of approximately 55,000 students over 1980.

We are providing $761 million for State programs for the aging, including the nutrition program of congregate and home delivered meals. Between 1980 and 1983 the number of meals increased by 22 percent, from 167 million to 203 million. We expect further increases in the number of meals served in 1984 and 1985.

Also, we are requesting $64 million to assist States in assuring that persons with developmental disabilities have access to a wide range of services enabling them to live as independently as possible.

Finally, we are requesting $217 million in the departmental management category, including the Office of the Secretary, the Inspector General, and the Office for Civil Rights. For 1985 our request includes staffing reductions in the Office of the Secretary based on initial recommendations of the Grace Commission. A significant portion of these reductions have already been met by transfers to the Department's operating divisions and by not filling positions vacated over the past several months.

## MANAGEMENT ACTIONS

I would also like to comment on the forceful management actions we are taking to assure that our dollars serve as many people as possible. This, too, we feel, is part of caring, and we have attacked fraud, waste, and abuse aggressively. Last year we ranked first in hotline calls received from citizens who wanted to blow the whistle on perceived wrongdoers. These calls are one of the reasons that our Inspector General has increased felony convictions by 700 percent since 1981.

I can also report specific steps which have reduced costs and improved efficiency. We collected $2.7 billion in debt owed to us in 1982 and 1983, and we expect to collect another $3.1 billion in 1984 and 1985.

The Social Security Administration is improving its computer systems to better serve the public, and we are reducing the paperwork burden on the private sector—by 32 million hours since 1981.

This budget represents my commitment to be a catalyst for caring and to be fiscally responsible to the American taxpayer. In almost every category we have sought to meet the needs as responsibly as possible.

That concludes my remarks, Mr. Chairman, and I would be happy to respond to your questions.

Senator WEICKER. Thank you, Madam Secretary.

Since we have several Senators here I will impose a 10-minute go-round on the questions, the chairman included.

### SPENDING FOR DEFENSE AND DOMESTIC PROGRAMS

Two comments, first of all. And you're free to come back at me with a rejoinder. You cited a great number of statistics, how many dollars were being spent by your Department, et cetera. I would like to cite to you the following statistics:

Outlays in 1980, defense was $133 billion; in 1984, $260 billion. Outlays in labor, health and human services, and education: $39 billion—talking about discretionary now—in 1980; it is $23 billion in 1984. Now that's the bottom line as to what our investments are in terms of the programs which you are in charge of, with the exception of that portion which is labor. I'm talking about discretionary. To me that's about as clearcut a picture as to what is happening in this country as anything that I can say as a matter of rhetoric.

How do you respond to those figures?

Secretary HECKLER. If you look at the timeframe between 1962 and 1982, a 20-year period, defense consumed 47 percent of the Federal budget in outlays, and health and human services consumed 28 or 29 percent in 1962. In 1982 health and human services consumed 47 percent of Federal outlays and defense 28 percent. So you have had an enormous shift in which the priorities have really changed dramatically in the country during that 20-year period.

Looking at the 4-year period that you are stressing, one can see that the pendulum is swinging back again. The radical change, the radical reversal of the pendulum occurred in the earlier 20-year period. Now there is an attempt by the administration to create a different set of balances.

I am most interested in health and human services programs and sympathetic to increases there, not only because that is my own Department, but an area in which I have a concern. But I also think, looking at the total needs of the country, the historic perspective of the 1962–82 figures is important.

Senator WEICKER. In all the testimony that we have had in the weeks prior to your appearing before us I don't think a person, either from NIH or from wherever, has indicated anything other than the breakthroughs of today being responsible or coming to pass by virtue of the commitments made 10 to 15 years ago. And I think the record should be made straight on that, Madam Secretary. Nothing is owed to this administration as far as these breakthroughs are concerned. I don't even know which administration, if we went back 10 to 15 years ago, was responsible. But the concern of this committee is not just to reap the benefits of previous investments, but to make sure the investments are made today which will bring to pass in the future the very things which you are extolling today.

Incidentally, if Claudia is correct, the statistics that you cite there include entitlements, don't they, Mr. Itteilag?

Mr. ITTEILAG. Yes; they do.

Secretary HECKLER. Yes; they do.

Senator WEICKER. Now let's stop confusing the issue. I am talking about discretionary spending. We all know what has happened to entitlements. And that is not what I'm talking about. I'm saying in the discretionary area, labor, health and human service, and education, you have gone from $39 billion to $23 billion in outlays.

Secretary HECKLER. That's true.

Senator WEICKER. A dramatic reduction. While defense has gone from $133 billion to $260 billion. Now you're not the Secretary of Defense and you don't have to relate to that. But you can sure relate to the discretionary area. It is this kind of fogging of the issue by the administration that really disguises what you are doing to emasculate the health and human services and education programs of this Nation.

### REDUCTION IN DISCRETIONARY PROGRAMS

According to my calculations, the amount available for discretionary programs in the fiscal year 1985 budget will be $1.2 billion less than the 1984 appropriations; is that correct?

Secretary HECKLER. Yes.

Senator WEICKER. Would you like to tell us why you think that is appropriate?

Secretary HECKLER. We are looking at a budget of $318 billion of which 96 percent, authorized by the Congress, is tied up in entitlements.

Given the budget deficit and the need to reduce spending, we have found many areas where we can reduce spending or hold the line and increase services, and I would point to congregate meals as one example. I also believe we have sound programmatic reasons for the reductions. For example, we have proposed elimination of the WIN Program, which has not been effective, for a reduction of $267 million; and the community service block grant, a position that the Department has taken for several years, for a reduction of $344 million. The reduction in the Refugee Program is due to reduced admissions and a lower number of eligibles under the existing laws governing the refugee populations and is not a reduction in services. So these programs have accounted for much of the reduction that we seek.

I would also like to say that the administration deserves credit for the breakthrough in support for research on Alzheimer's disease. This area of disease research has increased 31 percent since I became Secretary of this Department, and the encouragement of young scientists in searching for the answer on Alzheimer's as well as AIDS really is significant.

Senator WEICKER. Madam Secretary, I am not going to listen to that here. It was the Congress that put the money in for the research centers on Alzheimer's disease, not an administration request. It was the Congress that did that.

Secretary HECKLER. We requested an increase in Alzheimer's disease.

Senator WEICKER. You did not. The research centers were a matter of congressional action.

Secretary HECKLER. Yes; congressional action supported that, but the involvement and extension of research across the country was very much assisted by the support that we have given. For example, in 1981 the request for Alzheimer's was $16.7 million; today the request is $38.6 million, and we've had an explosion of interest among the scientists in Alzheimer's disease. I have worked very hard on this because I felt it was a priority that had not been recognized sufficiently in prior years. Breakthroughs are certainly to be hoped for given the brilliance of the scientists working on the research.

### FUNDING FOR NIH

Senator WEICKER. Not one word of testimony from the witnesses of the National Institutes of Health indicated that by virtue of the budget that they are submitting for fiscal year 1985 can they go ahead and increase the scope of their work. Not one word on that. In each instance they would have to cut back on competing grants, intramural grants, cut back on training programs, et cetera, by virtue of what was allotted to them. So when you say that under this budget you're going to be able to get an increased work product, not as far as the National Institutes of Health are concerned. We've just been through that whole gamut, and every one of those that testified indicated that these areas would have to be cut back.

Secretary HECKLER. In five of our institutes the funding for Alzheimer's disease increased from $16.7 million——

Senator WEICKER. I'm not talking about Alzheimer's disease; I'm talking about the whole range of work of all the institutes.

Secretary HECKLER. Well, I'm talking about Alzheimer's disease in which there has been a significant improvement. I mention that because I think it is important that the Alzheimer's breakthrough be encouraged.

I would agree with you, Mr. Chairman. If I were to lavish funds in any area of this budget, I would give most generously to NIH because the dividends are so great. But as we look at the fiscal constraints, decisions have to be made. The important thing that we have done is maintained the level of 5,000 new and competing grants which is indeed a step forward and a measure of revitalization and innovation at NIH.

Senator WEICKER. My time is up. I will again point out statistically that fiscal 1985 as compared to fiscal 1984 is 272 grants less—minus 272—in terms of competing grants compared to last year. That's the fact.

Secretary HECKLER. We have authorized 5,000 new and competing grants.

Senator WEICKER. You are 272 grants less, Madam Secretary, and if you want to, have your own budget director confirm that.

Mr. ITTEILAG. That is correct, Mr. Chairman.

Secretary HECKLER. May I ask John O'Shaughnessy to respond to this.

Mr. O'Shaughnessy. Sir, if I might, the policy has been to fund 5,000 grants. If they have found at the end of the year, funds were available, as had been the case in fiscal year 1983, NIH has funded more grants. They actually funded 389 more at the end of fiscal year 1983. The policy has consistently been a 5,000-grant level, but we have gotten a higher level because of changes in funding levels per grant in the course of the year.

Senator Weicker. The answer to that question, Mr. O'Shaughnessy was that the administration in last year's budget—I remember it well—wanted to go with 5,000 competing grants but get the money from the clinical trials and from the research centers, and the Congress wouldn't let the administration do that.

Senator Proxmire.

### EMPHASIS ON HEALTHY LIFESTYLES

Senator Proxmire. Thank you, Mr. Chairman.

Madam Secretary, I am delighted to see you. This is the first time I have had a chance to see you at a hearing since you and I were on the Joint Economic Committee. We miss you very much.

I want to congratulate you on your emphasis on lifestyle.

Secretary Heckler. You have been a leader in that yourself.

Senator Proxmire. And it is especially good that you dramatized the importance of diet with these delicious muffins that will enable us all to live forever. [Laughter.]

Secretary Heckler. No; those are Mrs. Andrews' muffins. [Laughter.]

Senator Proxmire. When you emphasize lifestyles it seems to me it is extremely important because it not only will enable people to live longer and healthier, putting more life in their years and more years in their life, but also save enormous amounts of resources. Expenditures in other areas are very important and very useful, and you and your predecessors have done a marvelous job over the years. But I think that changes in diet and in other living habits can be far, far more important. Dr. Knowles, who was in your Department years ago, said about 5 years ago that in the next 25 to 30 years this is where the real progress is going to be.

Secretary Heckler. Absolutely.

Senator Proxmire. So I am glad you emphasized the importance of lifestyles.

At the very beginning of your testimony you said that there is a prospect of an 80-percent reduction in cancer. As I understand it, about 35 percent of the reduction would be because of diet changes and 30 percent because of a decrease in tobacco consumption, so that two-thirds of the reduction would come from those two lifestyle changes.

Secretary Heckler. That's right.

Senator Proxmire. Those seem to be simple steps, and it seems to me that the cost is so much less in promoting that kind of behavior by our people so that we can make that kind of progress than in treating cancer once it has established itself.

I also want to congratulate you on the concern that you have expressed regarding medicare and medicaid. They certainly are marvelous programs. I voted for both of them, as I am sure you did, and I am delighted that you are emphasizing them. Also you have emphasized your concern over their immense costs. There is no federally funded program, defense or any other program, that over the years has grown and is still growing as rapidly as medicare is. We have to find ways of restraining that growth.

INDIRECT COST

On page 8 of your statement you say the following:

> The budget request is sufficient to provide a 5-percent increase over 1984 in the average research project grant award as well as provide for full indirect costs, though the administration remains concerned about rapid inceases in indirect costs.

As you know, the General Accounting Office recently came out with an indirect cost report indicating that over the past 10 years indirect costs have absorbed a greater and greater proportion of biomedical research grants awarded by NIH.

Indirect costs don't involve the money that goes to substantive research but cover overhead.

In 1972 one-fifth of each research dollar was spent on institutional overhead. By 1982 indirect costs claimed almost one-third of each research dollar, indicating a loss of efficiency.

The report inferred that one reason for this continuing indirect cost growth may be inadequate oversight by the Department. The GAO report indicated that the IG's Office had issued indirect audits on only 47 of an estimated 700 grantees under their jurisdiction receiving NIH research funds.

The Office of Management and Budget said they were concerned that HHS may be falling behind in its indirect cost responsibilities.

Do you have any plans to reemphasize the Department's responsibility to adequately monitor indirect costs?

Secretary HECKLER. Yes; we do, Senator. Last year we made a serious attempt to reassess indirect costs in dialog with university presidents and academic leaders. Dr. Brandt participated in this extensively. We're proud of our Inspector General as one of our most effective functions in the Department, and I am going to direct him to increase the number of audits in the area of indirect costs.

We feel that the indirect cost issue should not be assessed in terms of HHS grants exclusively. A common feeling among the university presidents and in our Department is that the issue should be Governmentwide because there are energy projects, defense projects and others that are also researched at the university level.

In order to find a fair solution and to produce equity I have asked Jay Keyworth, the President's scientific adviser, to undertake a study of indirect costs across the board in all departments. We expect from this some changes.

Senator PROXMIRE. Could you tell us when you expect a reply to your request?

Secretary HECKLER. I directed the request to him about 2 months ago, and I was supposed to meet with him this week.

Senator PROXMIRE. Do you expect to receive a reply momentarily or within the next few weeks?

Secretary HECKLER. No; I would expect a response, not a final reply. But I would be happy to share that with you, because this is an area in which we have spent a great deal of time.

[The information follows:]

### PROGRESS ON OSTP REVIEW

My staff has met with officials of the Office of Science and Technology Policy [OSTP] on two occasions during the past 2 months to discuss alternate approaches to the indirect cost problem. The most recent meeting was held on April 11, and included representatives from OMB and the National Science Foundation in addition to those from HHS and OSTP.

OSTP has not set a firm target date for submission of its recommendations, but is actively working on the problem and hopes to make recommendations before the end of the year.

### INDIRECT COST AUDITS

Senator PROXMIRE. I would appreciate it also if you would let us know roughly when you would expect a reply.

My question was directed at a GAO report statement that the IG's Office had issued indirect cost audits on only 47 of an estimated 700 grantees under their jurisdiction receiving NIH research funds. That seems to be a very small proportion.

Secretary HECKLER. I would say so. But if measured against the universe of HHS programs totaling $318 billion, and especially the entitlement programs it may not be unreasonable. Our Inspector General has emphasized looking at provider fraud. He is emphasizing that area because he feels that we are going to make greater progress in stemming fraud and abuse in these programs.

We are looking at the review of the indirect costs issue.

### AUTHORIZED POSITIONS

Senator PROXMIRE. The Grace Commission report on your Department says, "Open positions throughout HHS are traded among the agencies when there is money available. For example, if PHS has extra authorized positions but no money, it may give them to Social Security which may have the money but no authorized positions." Is this true? And if it is, doesn't that make your position justifications meaningless?

Secretary HECKLER. I think that that statement related to a prior timeframe.

Senator PROXMIRE. It is no longer true?

Secretary HECKLER. It is possible. Since the Grace Commission made its recommendations, I have issued a hiring freeze. I have also transferred staff to other segments of the Department. We are not increasing our hiring, except in a very limited number of areas, and one of the ways that we have reduced the FTE's in the Office of the Secretary by 1,200, as the Grace Commission recommended, was by out-transfer of functions. Ultimately we will have a very substantial reduction as a result of what we have done.

I would be happy to provide for the record any further elaboration upon how this has been done. Many of the changes have occurred through transfer into Social Security of functions which were being performed under the Office of Secretary account solely in support of Social Security's needs.

[The information follows:]

### RELATIONSHIP OF POSITIONS AND FTE

The Appropriations Committees have traditionally used the term position to make judgments on the staffing levels for executive branch organizations. A position is occupied by a full-time employee holding a permanent appointment. Congress has not applied the term to or in other ways measured other than full-time, permanent (part-time and temporary) staff.

The concept of full-time equivalent [FTE] is the measure used within the executive branch since fiscal year 1982 to determine staffing levels and manage them during the year. An FTE is a staffing unit representing one compensable work-year totaling 2,080 hours. Whereas the concept of position measures only full-time permanent employment, the concept of FTE measures all employment including part-time and temporary staff.

The Department does not trade positions. Position allocations made by the Congress through the annual appropriations process are not altered during the year except when the Department changes the organizational placement of a function. In such cases, authorized under the Secretary's general management authorities, certain activities and all dollar and staff resources may be transferred from one organization to another. The function and resource levels associated with it are not altered but are continued in its new organizational setting. Transfers of function are displayed and explained in the Department's annual justifications to the Appropriations Committees and are subject to action by the committees.

The Department and its components do have the flexibility to shift FTE. Each year, in the annual budget process, the Office of Management and Budget assigns the Department a fixed level of FTE which is a ceiling which cannot be exceeded. Within that total ceiling, the Department assigns FTE to its operating divisions and their components. As the year progresses, good management practice requires that use of FTE within these divisions be reviewed and that shifts be made to ensure the most efficient use of staff resources. Such shifts are not frequent and involve only a small fraction of total FTE available to an organization.

Such shifts do not involve changes in positions levels assigned by Congress, nor do they infringe on the intent of Congress in assigning these positions for the following reasons:

Position levels measure the maximum amount of full-time, permanent employees permitted to any agency. For a variety of reasons, most frequently normal vacancy rates, not all positions are filled at all times. Depending on the circumstances, the FTE associated with vacant positions may more profitably be used by another organization, and it is reasonable to make adjustments in FTE in such situations.

Shifts in FTE ceiling, unless associated direclty with a transfer of function, do not change or alter the nature of functions being performed by the Department. They do, however, permit maximum use of total staff resources.

Further flexibility is afforded the Department because FTE comprises all employment, including part-time and temporary staff not specifically controlled by congressional position allocations.

In preparing annual budget requests, the Department's components carefully asssess the level of positions justified by the program levels requested. These position levels are reflected in the annual justifications to the Appropriations Committees.

### SUBMITTING ADDITIONAL QUESTIONS

Senator Proxmire. Thank you very much, Madam Secretary.

My time is up, Mr. Chairman. I do have some questions for the record.

Senator Weicker. Indeed. And I plan to come back to the Senator.

Senator Proxmire. Well, I have to go to the floor. I will come back here if I can.

Senator Weicker. Senator Andrews.

Senator Andrews. Madam Secretary, it is good to have you here, and I am glad that you opened the hearing with your mention of the message you had gotten from NIH about bran muffins being nutritious and good for you and lowering your cholesterol, but the bran muffins you brought, I suspect, were made from a little lower quality wheat than the hard spring wheat we have out in North Dakota. So let me give you Mary's bran muffin recipe and a bag of our own North Dakota hard spring wheat bran so that you can make them the right way and lower your cholesterol and pass the word on to the NIH people.

Bill, here is the real thing. [Laughter.]

Senator Andrews. Bill is a skeptic, and he went to Dr. Carey and he said, "Does it work?" And he said, "You're right, it does. Hard spring wheat bran from North Dakota really works."

Secretary Heckler. Absolutely.

Senator Proxmire. Well, Mark, I can tell you if you butter these with Wisconsin butter and wash them down with Wisconsin milk you'll really—[Laughter.]

Senator Andrews. Mind you, if you look at Mary's recipe, Mary's recipe calls for using sunflower oil in making the bran muffins. You don't need butter on them. [Laughter.]

Mr. Chairman, I know where my bread is buttered, so here is your sack of bran too. [Laughter.]

Secretary Heckler. Thank you very much, Senator Andrews.

Senator Andrews. It will be good for you.

Mr. Chairman, I would like to put in the record at this time the news report from the Department of Agriculture dated April 13, 1978, when they found the unique characteristics of hard spring wheat bran, and then actually it seems that nothing was picked up on it. These are the kinds of research developments that mean so much to the future health of the American public, and I would hope they could be a little wider disseminated. Dr. Carey here on Capitol Hill has had me send these care packages to a number of our colleagues. They work, and I think maybe this might stir the imagination of some of the people if we put it in the record.

Senator Weicker. It will be included in the record at this point.

[The information follows:]

### HIGH FIBER DIETS MAY LOWER SERUM CHOLESTEROL LEVELS

(Atlantic City, NJ, Apr. 13)

Eating some experimental high fiber diets lowered the blood serum cholesterol levels of male volunteers by 12 to 17 percent in a preliminary human nutrition study, a U.S. Department of Agriculture [USDA] scientist reported today.

Dr. Juan M. Munoz, a medical officer with USDA's Science and Education Administration [SEA], detailed physiological responses to high-fiber diets at the annual meeting of the Federation of American Societies for Experimental Biology here today.

Dr. Munoz fed 15 volunteers bread supplemented with hard red spring wheat bran, finely ground soybean hulls, corn bran, soft white wheat bran, textured vegetable protein, apple powder or carrot powder.

Serum cholesterol levels were lowered significantly in the six males who ate diets containing bread supplemented with soybean hulls. Serum cholesterol levels were also lowered in the nine eating hard red spring wheat bran, Dr. Munoz said. The cholesterol levels of four of six men eating diets containing corn bran were also lowered.

Soft white wheat bran or textured vegetable protein generally failed to lower serum cholesterol, he said.

The 15 healthy men who volunteered for this study lived in the metabolic unit of SEA's Human Nutrition Laboratory, Grand Forks, ND, for 4 to 8 months.

Each participated in several 30-day phases of the research—eating a control diet or the control diet supplemented with one of several sources.

"We designed the control diet to typify diets of the United States," Dr. Munoz said. The experimental diets differed from the control diet only in that each day's bread contained about 26 grams (nearly 1 ounce) of the fiber source.

After the volunteers had consumed diets supplemented with finely ground soybean hulls for a month, Dr. Munoz and his colleagues found that total cholesterol levels in the blood plasma averaged 156 milligrams per 100 milliters. That was an average 14 percent decline from the cholesterol levels of the individuals when they were fed the control diet.

The researchers observed similar declines in total cholesterol when diets containing hard red spring wheat bran were consumed. Levels of low density lipoprotein [LDL] cholesterol associated with these diets were about 30 percent lower than levels associated with control diets.

Dr. Munoz found that eating corn bran, finely ground soybean hulls, apple powder, or carrot powder improved glucose tolerance—the ability of individuals to use carbohydrates efficiently. The study demonstrated, however, that not all sources of dietary fiber are equally effective in improving glucose tolerance or in lowering serum cholesterol.

The researchers at Grand Forks found that lowered levels of LDL and total cholesterol were generally associated with improved glucose tolerance. Further studies may help researchers determine how high density lipoprotein and LDL cholesterol levels, obesity, and changes in carbohydrate metabolism may relate to atherosclerosis, Dr. Munoz said.

Participating in the study were researchers of the SEA Northern Regional Research Center, Peoria, IL, and the SEA Spring and Durum Wheat Quality Laboratory, Fargo, ND, as well as researchers and volunteers at the Human Nutrition Laboratory.

### URBAN-RURAL ISSUE UNDER PROSPECTIVE PAYMENT

Senator ANDREWS. Madam Secretary, to get to the questions that I came with, I appreciate your action and your cooperation on our Minot Hospital. We are making some progress. But in your letter you pointed out that the changes you describe, made as part of the regulation to be published this summer, will apply to prospective payments made beginning by fiscal year 1985. That leaves our St. Josephs Hospital in Minot out $650,000. For a nonprofit hospital, how do we get that back? Mind you, you're up front in this letter. You're saying that we made a mistake and we're going to adjust it. But how can a nonprofit hospital recover from a $650,000 mistake?

Secretary **Heckler**. As you know, the designation of the urban and rural hospitals was based upon what we considered the reliable table published by OMB for such designations.

Senator **Andrews**. That's true, but it turned out not to be the case.

Secretary **Heckler**. Exactly.

Senator **Andrews**. And you're correcting it and we appreciate that. I think it's not just the case of the Minot Hospital but the case of a number of similarly situated hospitals.

Secretary **Heckler**. Under the prospective payment systems, we are required to have budget neutrality with the TEFRA system. So this is not an expanding pie.

Senator **Andrews**. I am aware of that. But I don't think that that requirement really envisioned the type of sandbagging that is going to happen to a number of nonprofit institutions from which they are going to have a difficult time recovering.

Could you provide for the committee or for my office some suggestions you might have as to what legislative action, what we might do in the committee to counteract this inequity?

Secretary **Heckler**. I would be glad to.

[The information follows:]

## RURAL HOSPITALS

As I stated in my March 30 letter, I have asked HCFA to reexamine the definition of regional referral centers. HCFA will be examining the problems of rural facilities which offer a comprehensive range of complex services, serve as regional resources and therefore have needs atypical of rural hospitals. I intend to have improved criteria in the proposed FY 1985 prospective payment regulation. I also understand that the Senate Finance Committee is considering a provision which establishes an appeals process for rural hospitals to be classified as rural referral centers.

In addition, we are prepared to study a proposal of the degree of variation in inpatient costs per discharge within each diagnosis-related group as suggested by the hospital industry.

Through these actions, as well as the other changes described in my March 30 letter, a copy of which is attached, I believe we will insure that the prospective payment system is fair and equitable for all hospitals. Therefore, I don't believe other legislative actions are necessary at this time.

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MAR 30 1984

As you know, nearly fifty percent of the nation's acute care hospitals are currently being paid according to Medicare's new prospective payment system. I am pleased to report that implementation of the system is going well and in general hospitals appear to be responding favorably to the incentives as we had expected.

Since October 1, 1983 when the new system began, I have received numerous letters concerning the different payment rates among regions of the country. As you know, the prospective payment legislation requires payments to hospitals be based on geographic settings, including geographic regions and urban and rural locations. These distinctions have raised a number of concerns. Congress mandated that the Department conduct a study of the need for urban and rural payment rates by the end of 1985. While I intend to be timely and commit considerable resources to this study, some of the concerns can and will be corrected as soon as possible.

First, I intend to correct the deficiencies in the application of the wage index which is utilized in developing hospital's payment rates. The Department is surveying every Medicare participating hospital to get an accurate count of their full and part-time workers. We expect development of this revised wage index will be completed in time for incorporation into the Fiscal Year 1985 prospective payment regulation.

Second, as you know current law requires use of the most recent urban metropolitan statistical area designations as determined after study by the Office of Management and Budget. The June 1983 redesignation resulted from the decennial census which shifted sixty counties from rural to urban and forty nine counties from an urban to rural classification. While there may be modest annual revisions, historically this process has yielded very few changes in designations; over the past 10 years, counties have been shifted only from rural to urban.

A third area of concern is that of the fourteen Metropolitan Statistical Areas (MSA's) which are bisected or in some cases trisected by a census division. The census divisions phase out entirely during Fiscal Years 1985 and 1986. However, in the interim, we believe it is more equitable to use a uniform geographic adjustment factor for these MSAs.

I intend to redress these problems by exercising my administrative authority within a budget neutral concept. I am concerned, however, that these changes may have an adverse impact in nearby areas, which I will seek to minimize should any occur.

There has also been considerable interest in classification of certain hospitals as regional referral centers. Accordingly, I have asked HCFA to review and reexamine the basis for determining the criteria for referral centers. Through this approach we will address the problems of facilities located in rural areas which offer a comprehensive range of complex services, serve as regional resources, and, therefore may have needs which are not typical of rural hospitals. It is my intention that an improved definition be included in the rulemaking for Fiscal Year 1985. Of course, payment adjustments to identify regional referral centers must be made in a budget neutral context.

Finally, it is our understanding that the hospital industry would like the Department to study a proposal on the degree of variation in inpatient hospital costs per discharge within each diagnosis-related group. We are prepared to initiate such a study and to submit a report to Congress on our findings.

We have all been very concerned about the high cost of health care. Cost reimbursement has been implicated as a major factor in the escalation of health care costs. Perhaps the most important feature of the new prospective payment system is the change from reimbursing individual hospital costs to establishing prospectively set rates which offer incentives for efficient and effective operation. I believe it is essential to keep on track and keep moving toward a national system.

The new system is fundamentally sound. The refinements I am developing are designed to allow facilities to operate, to the greatest extent possible, with certainty as to their status for payment purposes. Thus, hospitals would be able to plan their activities, and increase their efficiency, consistent with quality of care requirements. I believe this is preferable to approaches which emphasize the use of exceptions processes—which by their nature are disruptive, provide no assured outcome for the facility or for the government, and which in the end bring us back to reimbursing on a cost basis.

These changes I have described will be made as part of the regulations to be published this summer and will apply to prospective payments made beginning in Fiscal Year 1985. We do not intend to make any of these adjustments retroactively. Given the budget neutral provisions of the prospective payment system, upward retroactive adjustments to any hospital would require a corresponding retroactive decrease to other hospitals. Therefore, since one of the features of the new system is to set payments in advance so hospitals can plan efficiently, I believe it is only appropriate to make these changes prospectively.

The above mentioned items address the major issues which have been raised during the early implementation of the new prospective payment system for Medicare. The Department stands ready and is committed to make these modifications in the proposed rules for Fiscal Year 1985 early this summer. My staff will keep the Committee informed of our progress in these matters.

Sincerely,

Margaret M. Heckler

Margaret M. Heckler
Secretary

NIH BUDGET

Senator ANDREWS. Let me also add my feeling of concern to that of the chairman. I think he asked you some outstanding questions. When we had the hearings with NIH here they talked about the great things they were doing and the potential for the future and the fact that these investments pay dividends back 10 times over. You said exactly the same thing. In fact, you emphasized in your statement to us the great things that can come out of this kind of research. Yet we see sharp budget cuts as far as effective carrying on of this. How do you correlate the one with the other?

Secretary HECKLER. I said that I would understand lavishing extra funding on NIH because I think the dividend is great.

Senator ANDREWS. But in effect you're cutting the actual work that they can do by allowing only a 4-percent increase, as I recall.

Secretary HECKLER. We have a 5-percent increase for research project grants, an $89 million increase. Looking at the problems that we have, there are so many issues and the research is so superb that, obviously, one could spend an unlimited amount of money.

Senator ANDREWS. But in response to our questions, Madam Secretary, they said that they were going to have to cut back because of these cuts the young researchers coming on board, which meant that in the out-years, 5 years from now, a decade from now we won't have these developments that we would have otherwise, and in fact many of the breakthroughs that you are taking credit for now came about because people in their wisdom a decade ago kept these people in place. Recognizing that, I am sure you can realize the concerns we have on the committee.

Secretary HECKLER. I understand your concerns. I feel very strongly that their work is superb, and we can be very proud of NIH. It is the envy and the hope of the world as well as our own country. The fact of the matter is, as great as NIH is, there are fine scientists funded by research foundations; this is not the only source of research on important diseases in the country.

Senator ANDREWS. And nobody recognizes that more than the people at NIH. Many of the scientists from outside of NIH come in, participate in the NIH programs, pick up ideas and suggestions. As you know, there is a flow of ideas from within the agency out, and that is the thing that keeps it going. You can't say you are going to cut down on the agency and that is going to help the people on the outside. The people on the outside are the first to say you have to have a strong NIH program because it works with them and they take advantage of it, and the centers in Boston, Massachusetts, your own backyard, centers in St. Louis, down in Texas, out in California are all better because of the strength of NIH.

Secretary HECKLER. One of the key things that we have succeeded in doing is preserving the level of new and competing grants. This accomplishes the reinvigoration of the research system by new scientists. It is through this mechanism that bright new people are brought into the system. We have continued the 5,000 level, and this year I didn't have a fight with OMB about it because they did accept it.

Beyond that, now we have requested a total of 17,000 new and competing grants. If one looks at the universe of health problems, maybe 17,000 wouldn't be enough. But in a budget that is $318 billion, one has to draw the line. I think that the health of NIH and its security will continue, and I have been assured that it will not be jeopardized at the requested level.

Senator ANDREWS. But it doesn't keep up with inflation and it doesn't keep the new people moving in, and that is the thing that we are concerned about, Madam Secretary.

### HEALTH PROFESSIONS TRAINING

In the fiscal 1985 budget you have requested $20 million for family medicine residencies and training. Last year we appropriated $34 million for this program. In the written justification for this particular program, as submitted by your Department, it states that this program is designed to promote family practice, especially in underserved areas.

That is where the need is the greatest. I just came back from holding hearings in the west as chairman of the Select Committee on Indian Affairs. On Indian reservations the medical care is appalling. There simply aren't enough doctors. In rural mid-America there aren't enough doctors. I have counties that don't have doctors in my State, and this is the same story in a number of other counties out there.

How do we correct this thing if the administration insists on cutting back, cutting almost in half the one program that will stimulate these kinds of doctors going through school and being out there to serve?

Secretary HECKLER. I understand the problem and I also understand your perspective on it. I am going to be visiting some reservations next week myself.

Senator ANDREWS. What are you going to tell them? Thanks, but no thanks? We recognize you've got a problem but we are not going to do anything? We're cutting back the funds that would help?

Secretary HECKLER. Our $100 million budget for health professions education focuses on the most critical health education needs; $71 million will be allocated to medical education for the economically disadvantaged and minorities, and that's up $11 million. This will be supplemented by $82 million available in 1985 in the 1,645 schools' Federal student loan revolving funds.

Senator ANDREWS. I know all that. But the point is, Madam Secretary, you've got the program for family medicine residencies and training. You've cut it in half. There is another program that last year we funded $52 million for, nurses training, basic in these areas. Again, the rural areas, the Indian reservations are chronically underserved. Your budget request slashes that to $14 million, a 300-percent decrease, and we learned last week from Dr. Graham, the Director of the Health Resources and Services Administration, that he requested $86 million for nurses training.

I would appreciate it if you could explain how you arrived at and approved a $14 million allocation and ignored Congress and Dr. Graham.

Secretary HECKLER. Very difficult choices have to be made, and we were informed by the Institute of Medicine study which addressed the issue of the nursing supply situation that there is a surplus. All of our information and data on physicians indicates a surplus but a poor distribution.

Senator ANDREWS. That is fine, Madam Secretary, but the trouble is you are cutting out the programs that give us the very people we need in the underserved areas. Can you tell the committee of the intitiatives that you moved ahead on, since you say it's poor distribution, to satisfy the distribution problem? Have you taken this lessened amount and put it all in rural areas or all in Indian reservations? I doubt that you have. I don't see it. How do you answer the problem. You just said that there are areas in this country that are critically underserved; there are other areas that are surplus in doctors and nurses. Do we wander around in the areas that are surplus and get a self-satisfied smile on our face, hide our heads in the sand and say the problem is nowhere amongst us?

Secretary HECKLER. We have, especially in terms of nursing, tried to allocate funds in this budget for training to the specialties in which there is not a surplus. An example would be the geriatric area. We have based our request on the information from the Institute of Medicine study which said that there is generally an adequate supply of nurses but not in every category of nursing.

### NURSES IN UNDERSERVED AREAS

Senator ANDREWS. Madam Secretary, you've got to get the basic nurse before you can decide whether they are going to be geriatric nurses or whatever else. Wouldn't there be someone in your Department with enough smarts to come up with the idea of maybe focusing these training incentives into those areas that are underserved, pick the universities that have nurse training programs in the areas that are deficient in their supply of nurses and augment those programs, pull the programs out of the areas that are overserved and that have a surplus? There is no sense in continuing to produce green cars if everybody wants a blue car, and it is idiotic to produce individuals that will serve in an area that is overserved when there is a crying demand for training individuals in underserved areas. Could you do something like that?

Secretary HECKLER. You make a good point, and I will investigate it with Dr. Graham.

Senator ANDREWS. Do you think that the committee should maybe direct you toward that goal? Can you expand on your answer at this point in the record so that we can have a look-see at what you might prioritize?

Secretary HECKLER. I would be glad to expand in the record. I feel that our emphasis on training nurses of certain specialties reaches the key nursing needs in the country. We have, I have been told, a number of wives of Members of Congress who are nurses; we have literally thousands and thousands of nurses in the country who do not practice nursing. We can train them indefinitely, but if we do not actually meet, as you say, the geographic needs for dispersion and distribution, then we have a problem.

Let me look at that. I will respond.

[The information follows:]

### FEDERAL ROLE IN NURSING EDUCATION

The administration's budget for fiscal year 1985 calls for a more focused Federal contribution to nurse training than was the case in the 1960's and 1970's. We see the Federal role as serving as a catalyst to address remaining problems, such as rural nursing shortages, by enlisting greater support from States, local communities, health care organizations, and professional associations for the improvement of nursing education and practice. We believe that the $1.9 billion spent between 1964 and 1984 in Federal support for nursing program has opened the way for a more highly selective Federal presence over the next few years.

While the bulk of the training effort for nurses is in programs which are national in scope, more than one-third of the 60 nursing special projects currently focus on enhancing the nursing services in rural areas. These projects increase the numbers and skills of nurses who are unable to go to metropolitan educational centers and who most likely remain and work in these rural locations. This awarding of nearly one-third of the program's total grants represents a recognition of rural nursing supply problems and a willingness to assist in solving them.

For example:

Presentation College has a satellite nursing program on the Cheyenne River Sioux Reservation in South Dakota providing theoretical and practical training in nursing, leading to an associate degree in nursing. This will provide native Americans the opportunity to become registered nurses with expectation that they will upgrade the health care of their people.

South Dakota State University has a program to train graduates of diploma or associate degree programs to earn a baccalaureate degree in nursing. This type of training is needed to prepare for a community health nursing practice of the type needed in rural areas.

The South Dakota State University at Brookings has a program which promotes and coordinates a statewide system of continuing education for all registered and licensed practical nurses in South Dakota. It does this through a network of eight geographically dispersed facilitators and focuses on the needs of nurses in rural, isolated areas.

In addition, all of the area health education centers program [AHEC] grantees work to increase the numbers and the training level of nurses in remote areas. Well known examples of this effort are the statewide AHEC programs in North Carolina and Ohio which have focused intensely on increasing educational opportunities for rural nurses for several years.

### UNDERSERVED AREAS NURSE SHORTAGE

Senator ANDREWS. But when you go to Bowbells, ND, you can't find a nurse; or Pingree, or wherever; and that is duplicated in South Dakota, Nebraska, in parts of all mid-America, and that is what we ought to direct our focus toward as long as there are those underserved areas.

My time is past up. I appreciate your understanding, Mr. Chairman.

Senator WEICKER. Thank you, Senator Andrews.

I asked that the figures be brought up relative to the Alzheimer's question, and these are the actual budget figures. The administration's request, the Alzheimer's request for all of NIH for fiscal year 1984 was $19.3 million. The Congress appropriated for fiscal year 1984 $31.5 million. That is the history of the matter. I appreciate the good intentions of the administration, but again it was left to the Congress to go ahead and supply the dollars.

### GUIDELINES FOR DEVELOPMENT OF FISCAL YEAR 1985 BUDGET

During the course of these hearings in the past week we have heard a lot about budgetary guidelines under which you were laboring. Just precisely how are those guidelines set and what role did you play in the process?

Secretary HECKLER. At an early time, as the budget was about to be drafted, the Budget Review Board met with me to discuss the general interests of the administration and what their goals were and what my goals were. Within that context, I met with the heads of the operating divisions of my Department.

I wanted to combine sensitivity and responsiveness with fiscal restraint. We have an enormous budget deficit in this country. I asked heads of my operating divisions to submit their concerns and to analyze how we could achieve more within existing funding levels or in what areas we had to make changes.

These issues were resolved by the division heads working with me last summer. We made presentations to OMB in September. OMB accepted some proposals and did not accept others. It was a give-and-take situation which continued through extensive negotiations. In the end, I appealed for 270 million dollars' worth of reductions made by OMB and received $235 million.

Senator WEICKER. At what point in the process did you seek the advice of those in the Department, such as Dr. Brandt? Was that before or after the so-called Budget Review Board gave you a target?

Secretary HECKLER. Immediately after; it was the very same day.

Senator WEICKER. After they gave it to you?

Secretary HECKLER. I had had a general discussion with the division heads. After I understood the administration's concerns and parameters, I certainly wanted to be responsive to the Budget Review Board and its direction and at the same time be responsive to what I considered to be the needs of my Department. So I met with Dr. Brandt and the senior staff and the heads of the operating divisions that very same day. At that point we were speaking within a contextual framework that was not a precise dollar figure.

Senator WEICKER. Whose decision is it as to what will be available for the Health Resources Administration or NIH?

Secretary HECKLER. All of these have come as a result of exchanges of perspectives between Dr. Brandt and the heads of the Health Resources Administration and NIH and, in turn, between Dr. Brandt and myself, and finally, between myself and Director Stockman on a number of issues.

Senator WEICKER. Was it your decision or OMB's to once again seek zero funding for the community services block grant?

Secretary HECKLER. This is a pronounced and well estabished position of the administration, and it was not at issue between HHS and OMB.

Senator WEICKER. Who decided to hold low-income home energy assistance to $100 million below the fiscal 1983 funding level?

Secretary HECKLER. I was interested in increasing low income energy assistance over the 1983 President's budget, and we had many discussions on that. We did increase it, and as you know, we also got a supplemental, and I was very much a part of that.

### DEPARTMENTAL MANAGEMENT

Senator WEICKER. We did not receive your departmental management justifications until March 21. Ordinarily those documents are due the day the budget is submitted, which would be February 1. How can you justify this delay and the fact that nobody ever extended the committee the courtesy of a letter of explanation?

Secretary HECKLER. Our documents were being developed. This year we had some very unusual needs and very sensitive issues to resolve based upon the recommendations from the Grace Commission. We had to plan implementation of a reduction in staffing that would meet the needs of the Department, be fair to the employees and, address the Grace Commission recommendations.

This was a time-consuming process because we had to assess workloads in the Department and determine how many people could be transferred to other divisions of the Department, et cetera. All of these things were so time-consuming and so sensitive that a fast, immediate answer was not possible. We tried to address the employees' needs as well as appropriate reductions as carefully as we could. We have come out with a good plan that will reduce employment on a very humane basis, largely through transfers out and attrition. Sadly, a few will have to be separated.

Senator WEICKER. In a document explaining your proposed reduction of budget staff in the Office of the Secretary it says you plan to limit "the amount of assistance to the staff of congressional appropriations committees on low priority technical matters."

Last November Senator Proxmire and I wrote you a letter concerning technical budget matters pertaining to the Administration on Aging. On March 16 I got a partial reply from Mr. O'Shaughnessy, your Assistant Secretary. On March 29 I got a reply from you on this matter.

Do you call a 4-month delay in responding to the chairman good service to the committee?

Secretary HECKLER. We shall try to do better.

Senator WEICKER. Last, I would like to again set the record straight on the matter of NIH. There is no 5-percent increase that was requested. The increase was about 2 percent for NIH. The administration's inflation projection is 4.7 percent. So that automatically indicates where we stand insofar as that matter is concerned. It is not an increase; it is a decrease. And if you use the Congressional Budget Office as far as the inflation rate in the field of science and medicine, that is even higher, 6.9 percent.

Madam Secretary, before I turn to my good friend Senator Chiles, I have to say this. The rhetoric I applaud; the funding in order to make that rhetoric come to pass and become reality, that just hasn't been there. That has been the Congress. The Congress has had to step up to bat and make those hard decisions. I would hope that the time would come when you would do as well for your Department as Mr. Weinberger does for his and then you and I wouldn't have to go ahead and fight.

Senator Chiles.

### SYSTEMS MODERNIZATION

Senator CHILES. Thank you, Mr. Chairman.

Madam Secretary, we are delighted to have you here. You may want Mr. Mandell to help in answering some of these questions.

In the original systems modernization plan the Social Security Administration planned to produce manuals and written descriptions of the existing software and systems and to improve software maintenance and modification documentation of computer systems, and that was supposed to be completed by March 1984. What progress have you made in that connection?

Secretary HECKLER. I will ask Mr. Mandell, who is the expert in this field, to respond.

Mr. MANDELL. Senator, I think we have made quite significant progress in improving a lot of our software. That obviously has been reported over the last 10 years to be certainly outdated, and that is understandable. I think we are pretty much on target with our program.

In some areas we have opted, based on getting into the actual execution of the plan, not to improve some of the software. We made that assessment because some of the software was just so bad and so outdated and didn't really support a modern business processing environment that we opted to actually reengineer some of it. I'm really talking about our title II system. In that particular system we have improved a lot of the software just to help our overall maintainability, but at the same time we have initiated a number of efforts that will really bring to bear a complete new processing system. We feel that is a much more effective way of providing the services that SSA should render to the public.

There is still a lot of software to be improved. I guess I could say that the SSA environment in terms of its data processing systems certainly suffers from 10 years of decay and you are not going to repair it all in a 2-year timeframe.

I think equally important as just the actual fixing of the software are some of the management disciplines that have to be put in place so as to prevent that same software from falling back into the same posture that we found it in, and I think we have instituted a number of engineering disciplines which will prevent that from happening also.

Senator CHILES. If it is taking some time to redesign those software systems, how do you go about implementing the legislative changes in the meantime if your staff has hundreds of programs and systems without written details on how to use them?

Mr. MANDELL. If you look at the 1983 amendments, which certainly were very significant with respect to changing our software systems, we expect to implement all of those amendments on time. Again, I think we have brought to bear some very sound management practices. In the past nobody controlled SSA systems as to who can change it, when they can change, how they can change it. One of the first things we did when we instituted the modernization plan was take a complete inventory of every piece of software. That was the first time, I think, in SSA's history that the software had been completely documented, what it was comprised of and a complete assessment of all of that software.

Senator CHILES. Do you have documentation to show how those work?

Mr. MANDELL. We have a complete inventory now.

Senator CHILES. Not an inventory now, a documentation. I understand there is a difference between inventory and documentation.

Mr. MANDELL. If you are asking if every piece of software is documented, it is documented in some form.

Senator CHILES. I guess what I am trying to find out is can the contractors design a new system if you don't have a documentation of the old system?

Mr. MANDELL. Yes; in other words, in a lot of the new systems we are designing we are really doing what we call a top-down analysis, or taking a functional viewpoint of the entire SSA business process. We don't want to base a lot of our new systems designs on the old functional way of SSA doing business, which was vastly different from the way we want to see them do business in the future.

In terms of the software improvement effort, one of the first steps in software improvement is to take existing undocumented programs and run them through tools which will complete the documentation effort in an automated fashion, and we have been following that practice.

### SECRETARY'S REVIEW OF SSA SYSTEMS

Secretary HECKLER. Senator, may I just interject. This year, because I had many, many misgivings about the software system and our computer system at Social Security, having been alerted to it by others, I asked one of the most eminent experts in the field to review the situation. He is part of the new Executive Exchange Program, a former head of management information at TRW, who volunteered to undertake a review of the computer technology at SSA and to report to me on potential integration of existing technology and new technology. I was expecting to receive a report on a jerry-built system that was simply never going to be relevant and effective and reliable.

Contrary to my expectations, Frank Koch, who is the gentleman involved, reported back to me that these different computer systems, although bought in different eras, and having different types of software, were compatible. I would be happy to have him meet with you as well as to have Mr. Mandell meet with you in the future.

This was very reassuring to me, because I had major concerns and apprehension about the state of the technology at Social Security where we rely on technology so basically and essentially.

If you would like that, I would be glad to have Mr. Koch visit with you.

### SSA SYSTEM SECURITY

Senator CHILES. Fine. We may well want to do that.

In our report on the 1984 appropriations this committee raised concerns about system security. Specifically we asked about the status of the improved security measures, such as the issuance of personal identification numbers to all users on the telecommunications system. In your response to the committee in February 1984 you report using a personal identification number technique for having employees log on and off terminals used in field offices for claims processing and other data. The response goes on to say that the log-on/log-off has been effective as a security system based on security reports from both local and regional offices.

What supports that contention about the effectiveness of the log-on/log-off use of the personal identification numbers? And are you aware of any specific security problems associated with the technique?

Mr. MANDELL. First off, let me say that the SMP is certainly committed to improving security and it addresses security both in the short-term perspective and also looking at it in more depth over the longer term redesign activities. We have implemented a personal identification number for everyone that has access to a terminal; everyone is assigned a personal identification number and there are passwords associated with the PIN, and those passwords are now changed on a weekly basis.

That process has been implemented throughout all SSA field offices. We feel that in itself is a big deterrent to individuals trying to defraud the system.

Looking ahead to the future redesign activities, we have taken the PIN number even a step further. As it exists today it is used to gain access to the system. In the future, as we reengineer all of our claims processing systems, the PIN number will stay with a transaction for the life of that particular transaction so we will be able to backtrack at any time out into the future any event that took place on any SSA system and tie it to an individual.

So we have addressed it from the short term to make sure the PIN now is being used by all of our employees. In the future, as I say, I think we will even strengthen the use of the PIN.

I feel at this particular point in time that means at least the identification of individuals, being able to track a transaction to a person, goes a long way.

### OPERATIONAL PROBLEMS WITH SECURITY PROCEDURES

Senator CHILES. Are you aware of any operational problems associated with the personal identification number?

Mr. MANDELL. The only operational problems that I think we are possibly aware of is someone could exchange a PIN number. In other words, they could pass it along to another individual. We have been aware of that and we have made note of that to all of our regional security officers who do a lot more audits, spot checks out in the field. So we feel we have taken a number of steps to cut back on any unauthorized exchanging of the PIN number. I think also being able to tie an event to an individual basically deters the individual from passing his or her PIN number on to someone else to use.

Senator CHILES. I understand the Inspector General's Office in the Department has said that the personal identification numbers being assigned to individuals should not intitiate transactions and that they are being used interchangeably by more than one individual, which you have indicated, and that the personal identification number and related signature files are not being kept under lock and key, signatures are not always matched, and sometimes the forms are initialed rather than signed. All of that seems to tell me the bottom line is it would be easy for someone to obtain and complete a payment form and have a payment generated.

What keeps someone from literally resurrecting the dead in terms of getting Social Security benefits?

Mr. MANDELL. Obviously if someone is going to go to the extreme to defraud it they can, whether it be a banking system or the Social Security system. I think you have evidence of that every day.

Senator CHILES. That doesn't give me great comfort, that statement, because there are a lot of people that would like to defraud the Social Security system, and you say if anybody wants to defraud it they obviously can, and then we're in for real trouble.

Mr. MANDELL. I think we have taken significant steps forward with the PIN number. We are also working with the Defense Department right now in a cooperative effort on a security package called top secret which will also provide certain access controls into the system and into our data bases. We are putting in a new telecommunications system which will have additional security features. All of these take time.

I think the nationwide use now of the PIN number and the added emphasis that our field office security staff are placing in terms of doing random checks has in fact deterred this area that you cite.

Senator CHILES. My time has expired. I have some more questions for the record.

Senator WEICKER. Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman.

Madam Secretary, I compliment you on your work on the homeless. I think you are doing very good work and it is very needed. And I thank you for the biscuit. It was very good.

## PRIOR YEAR CLAIMS

I am advised that there are some 11 States, Madam Secretary, including Pennsylvania, Connecticut, and Wisconsin, which have not received long-awaited medicaid back claims from before 1978, which amount to some $7 million for Pennsylvania, and I am told that HHS had the money appropriated in 1981 and the Congressional Budget Office rates it as a no-cost item.

Do you have any knowledge of that situation?

Secretary HECKLER. I would have to provide that for the record, Senator. I am not familiar with that.

I have information from the staff that says in 1983 the continuing resolution requires these claims to be paid over a 3-year period in accordance with a payment schedule to be established by the Congress. No payment schedule has been enacted by the Congress, according to this information.

Senator SPECTER. I am told that there have been court rulings in the district court in Pennsylvania back in July of last year on this.

May I ask you to take a look at that? It's $7 million.

Secretary HECKLER. I will. I would prefer to give you a more detailed response.

[The information follows:]

The claims that you are referring to are pre-fiscal year 1979 claims which the U.S. Court of Appeals for the District of Columbia Circuit ruled must be paid in the case of *Connecticut* v. *Heckler*. These claims are to be paid out of existing funds from the fiscal year 1981 appropriation. Section 136 of the fiscal year 1983 continuing resolution (Public Law 97-276) prohibits the Department from paying any pre-fiscal year 1979 claims with the exception of those claims involved in the court case, which are to be paid over a 3-year period between fiscal year 1984 and fiscal year 1986 according to a schedule to be established by Congress. Both the Senate and the House now have provisions in their reconciliation bills establishing such a schedule. With regard to Pennsylvania, there are approximately $6 million in prior year claims, involving the medicaid, foster care, and child support enforcement programs, which are programmatically allowable and will be paid once the payment schedule is enacted.

## RUNAWAY YOUTH BUDGET

Senator SPECTER. I would appreciate that.

Madam Secretary, the runaway youth issue is a very serious one. I see it a great deal in the Juvenile Justice Subcommittee which I chair, and the administration has asked for $10.5 million; the Congress appropriated $23.250 million in fiscal year 1984, and we were very close to a $25 million appropriation. My sense is that this is a very small sum of money with more than 1 million runaways and abducted children and the tremendous problems in this area.

I would like your thinking as to whether we might not have your Department's cooperation in greater appropriations in that area.

Secretary HECKLER. As you know, there was a one-time infusion of extra funds into the Runaway Youth Program last year. What has happened this year is that we have returned to the historical level of funding.

Part of the reason for not seeking greater funding was the recognition that the major breakthroughs among runaway youth have come from private sources. We as a department have provided backup funds, but there are so many groups funding operations in various cities and States, that the Federal role is only a supportive one. We are not the main player in terms of the program itself.

Senator SPECTER. Madam Secretary, that is not so. The year before, in fiscal year 1983, we had it up to $18.5 million. Each year this committee has disagreed with the administration on that and has more than doubled what the administration has asked for. We have had a lot of hearings in the Juvenile Justice Subcommittee, and the facts are—and I visited many homes—that the Federal money is seed money and it is leveraged, so that for every dollar that the Federal Government puts up there are several dollars on the local level.

I would ask you to take a look at that.

Secretary HECKLER. I will.

Senator SPECTER. I would not be surprised if our subcommittee and the full committee raises your figure. But I would appreciate it if your Department would make an evaluation of that to see if we can't come closer together in the thinking of the Congress and the administration on that item.

Secretary HECKLER. I will certainly reexamine it.

Senator SPECTER. Thank you.

### REDUCTION IN MEDCAID

I am concerned about the reduction in the Federal medicaid payments to the State, Secretary Heckler. I know that in our 1981 Omnibus Budget Reconciliation Act we have provided for a reduction in payments which are now very substantial in the aggregate—3 percent in fiscal year 1982; 4 percent in fiscal year 1983; 4.5 percent in fiscal year 1984; and now the Department of Health and Human Services budget proposals for fiscal year 1985 include another 3-percent reduction in Federal medicaid payments to the States. This has an enormous impact all across the country, illustrated not only by Pennsylvania. Ours is not the only State. As I travel through the State and visit hospitals and talk to people in the field, they are complaining about the enormous crunch here.

My question is, realizing the difficulties you have in making ends meet everywhere, couldn't something more be done in this line?

Secretary HECKLER. As you know, the Congress mandated the reduction in 1982 through 1984, and this was something that our Department supported.

There are some interesting studies being done on medicaid. In addition, the Rand study indicated that the lesser access and lower usage did not change the healing pattern nor the degree of illness, and that, for example, a hospital such as the Mayo Clinic has a 40-percent shorter hospital stay than others and yet obviously has a magnificent healing record; that in fact the low-income person under medicaid has increased the number of doctors visits over that of the average person. What we are faced with is the enormous growth of medicaid, and the need to search for a way to deal with that growth while minimizing the impact on beneficiaries.

### MEDICAL COST CONTAINMENT

Senator SPECTER. Secretary Heckler, where do you think we are heading on cost containment in hospital costs, medical costs?

Secretary HECKLER. We have made a major breakthrough in terms of the prospective payment system. It is a beginning, but it is not going to deal with the whole problem.

I believe if medicare had been designed on a prospective reimbursement basis we probably would have avoided much of the health care inflation that has occurred in the last 17 years. Prospective payment is a first step, but I think the most encouraging factor in our society in terms of cost containment in health care is the development of the competitive medical marketplace.

We have just finished the HMO regulation allowing for medicare reimbursement at 95 percent of cost for senior citizens who choose to go to an HMO. There are new, innovative approaches in virtually every State and region, and I think this is our best hope of curtailing medical cost inflation.

Awareness of these new possibilities, and health promotion is important. The more I learn about how lifestyle habits can prevent illness, not only for cancer, but for at least half of the major diseases, the more I understand how important health promotion is to controlling costs.

Where are we going in terms of health care? I think that the American public has to realize that the best health insurance policy they have is a change in their own lifestyles, controlling their own daily options to preserve health.

Second, the really important encouragement is competitive health systems, health opportunities that are discounting costs and allowing people to get more for their health care dollar. Industry is way ahead on this, and it is really happening.

Our prospective payment is another important breakthrough; it's a change; and we have to stay the course there to get any advantage over the next 4 years.

So there is a lot that is happening that is worthwhile.

### CONSUMER AWARENESS IN HEALTH COST CONTAINMENT

Senator SPECTER. I have introduced legislation on a study for a limited exemption from antitrust liability for health care insurance, which would allow insurers to collect and use health care data to evaluate the cost and quality of various health care services and to provide consumers with information about the cost and quality of health care to allow them to make informed choices and to negotiate joint agreements with health care providers that will stipulate levels of care and cost for consumers so that there can be some overall control.

Do you have any sense as to the desirability of having that kind of activity by health care providers?

Secretary HECKLER. I certainly would agree with your goals. I think that consumer education is critical to the utilization of alternative health care schemes. The consumer has to become an aware and prudent buyer in the medical marketplace. Whether or not the antitrust exemption is the best way to achieve it is something I would have to think about further.

Senator SPECTER. Madam Secretary, perhaps I could ask you to take a look at S. 2051 and give me a comment on it. We have not yet held hearings in the Judiciary Committee, but I would be very grateful to you if you would take a look at it.

Secretary HECKLER. I will be very happy to.

[The information follows:]

### VIEWS ON S. 2051, HEALTH CARE COST CONTAINMENT ACT OF 1983

A report on the bill is being prepared by the Department, and it will be sent to you, through our General Counsel's Office, as soon as possible. This report will require clearance by the Office of Management and Budget.

### DEBT COLLECTION

Senator SPECTER. Thank you very much, Madam Secretary.

Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Specter.

Senator Proxmire.

Senator PROXMIRE. Madam Secretary, last year in response to a question submitted for the record you said that the Department collected $1.2 billion in delinquent and nondelinquent debt in fiscal year 1982. Your 1983 debt collection target was $1.4 billion. Did you meet that target?

Secretary HECKLER. Yes; we did. We exceeded it—$1.5 billion.

Senator PROXMIRE. Very good.

Last year you indicated your debt collection goal for fiscal 1984 was $1.6 billion. Is that goal still attainable, in your judgment?

Secretary HECKLER. Yes.

Senator PROXMIRE. What is your debt collection target for fiscal year 1985?

Secretary HECKLER. It is $1.6 billion.

Senator PROXMIRE. My next question has to do with a very small amount of money, but it is symbolic. Last year you told the committee that five HHS employees were being assessed for Department of Education indebtedness. However, the Department of Education has informed us that 625 of your employees have defaulted on $800,000 in student loan funds. Why haven't you been able to reach those employees?

Secretary HECKLER. We have subsequently learned that only 450 of them are currently HHS employees, and we have informed those employees of their responsibilities. Beyond that, OPM is considering a new regulation which would allow any department to offset against salaries the indebtedness for student loan delinquencies.

Senator PROXMIRE. Garnishments.

Secretary HECKLER. Yes; and when that is done we will certainly comply. Indeed, we will be very happy to.

We also sent a letter to every employee discussing this issue, and we specifically informed employees who are currently with the Department of their responsibilities and how to go about repayment, and so forth.

Senator PROXMIRE. Could you give us just a rough notion of how big the proportion of those with delinquent student loans is? I know it is difficult and I don't want to be unfair to you , but I would like to relate the number of delinquent debts to the number of people you have working for you who have student loans that they are paying off. I want to compare the delinquents to those who are not.

Secretary HECKLER. I don't know the total universe.

Senator PROXMIRE. Are 1 percent or 10 percent of the outstanding loans delinquent? Can you give us any notion?

Secretary HECKLER. We would have to supply that for the record.

I believe the major breakthrough would be the offset of salary; if we can have a salary offset the student loans will be paid quickly.

[The information follows:]

### DEBT COLLECTION

The Department of Education [DEd] does not have a record of all student loans, including those that are not delinquent. However, the national average of all student loans that are in default is approximately 10 to 12 percent. DEd believes the percentage of Federal employees that have defaulted on their loans is considerably less than the national average.

As of March 30, 1984, 82 HHS employees had paid their delinquent loans in full and 123 were paying under an agreed repayment arrangement. The balance of delinquent loans will be collected by salary offset as soon as the appropriate regulation is in place.

### ASSESSING DELINQUENT EMPLOYEES

Senator PROXMIRE. You have assessed five HHS employees. Why can't you assess all of your delinquent employees?

Secretary HECKLER. I would like to have John O'Shaughnessy, who has been active in this field, respond.

Mr. O'SHAUGHNESSY. We have to have the regulation in place before we can take positive action to assess these employees. Until such time, however, we have acted to bring it to their attention in order to get them to do it. The five was a low estimate; the actual number was 450.

Senator PROXMIRE. Did those five employees voluntarily pay? I don't see how you can get at five and not get at all of them.

Mr. O'SHAUGHNESSY. We intend to get at all of them, with no exceptions. The estimate was originally five; the actual is 450.

### WOMEN AND MINORITIES IN SES POSITIONS

Senator PROXMIRE. Last year, Secretary Heckler, in an answer submitted for the record you told us that of the 546 senior executive level positions only 80 were held by women and 48 by minorities, 15 percent and 9 percent of total positions, respectively. Although 44 percent of promotions to grade 12 and above went to women in fiscal 1982, the proportion of women and minorities in executive level jobs in the Department remains quite small.

Can you update your statistics on senior executive service and executive level positions held by women and minorities and tell us if you have any hiring and promotion goals for either women or minorities?

Secretary HECKLER. We have made a very strong effort to recruit women and minorities. Recently I established two task forces on women's employment. One will develop an agenda for improving the status of women at the executive level in the scientific occupations where the record is poor compared to general schedule scientific staff. The other focuses on senior and executive level positions in general.

Senator PROXMIRE. Is the record extremely poor because it is hard to find women who have that kind of educational background, or is the record poor because there just hasn't been that sort of ongoing effort on the part of the Department, or both?

Secretary HECKLER. As a member of the Science and Technology Committee of the Congress I worked very hard on women and minorities programs. At that time we had very few women who were in the Ph.D. category primarily because of the old boys network which didn't encourage women to develop their talents in the field. I find that in our Department, which relies, especially at NIH and CDC, so heavily on scientific expertise, the number of women is very small. I will say, however, that three out of four of the major components of HHS are headed by women: Carolyne Davis, Administrator of HCFA; Martha McSteen, Acting Commissioner of Social Security; Dorcas Hardy, Assistant Secretary for Human Development Services. Also my Assistant Secretary for Public Affairs is Stephanie Lee-Miller, who happens to be black and a very, very competent, excellent woman. Betty Lou Dotson directs the Office for Civil Rights; Teresa Hawkes is the Deputy Assistant Secretary for Legislation.

What we have done is search out the methods of developing women and minorities in the work force at HHS.

Senator PROXMIRE. For the record, will you give us the updated statistics on the number and percentage of women in senior executive service?

[The information follows:]

# DEPARTMENT OF HEALTH AND HUMAN SERVICES
EXECUTIVE LEVEL EMPLOYMENT
CALENDAR YEARS 1981-1983

| Categories, Minority and Total | Public Health Service |  | Health Care Financing Admin. |  | Social Security Admin. |  | Human Development Services |  | Office of the Secretary |  | Department of Health and Human Services, Total |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
|  | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % |
| **Women** |  |  |  |  |  |  |  |  |  |  |  |  |
| Dec. 31, 1981 | 34 | 9.8 | 4 | 10.5 | 11 | 19.6 | 4 | 30.8 | 15 | 18.9 | 68 | 12.7 |
| Dec. 31, 1982 | 32 | 9.7 | 4 | 10.3 | 16 | 24.2 | 3 | 25.0 | 18 | 20.0 | 76 | 13.6 |
| Dec. 31, 1983 | 35 | 10.4 | 7 | 17.5 | 16 | 23.5 | 3 | 27.3 | 19 | 21.8 | 80 | 14.6 |
| Change, 2 year Period | + 1 |  | + 3 |  | + 5 |  | - 1 |  | + 4 |  | +12 |  |
| **Black** |  |  |  |  |  |  |  |  |  |  |  |  |
| Dec. 31, 1981 | 22 | 6.3 | 4 | 10.5 | 6 | 10.7 | 1 | 7.7 | 7 | 8.9 | 40 | 7.5 |
| Dec. 31, 1982 | 20 | 6.1 | 4 | 10.3 | 7 | 10.6 | 2 | 16.7 | 7 | 7.7 | 43 | 7.7 |
| Dec. 31, 1983 | 22 | 6.5 | 4 | 10.0 | 7 | 10.3 | 1 | 9.1 | 7 | 8.0 | 41 | 7.5 |
| Change, 2 year Period | --- |  | --- |  | + 1 |  | --- |  | --- |  | + 1 |  |
| **Hispanic** |  |  |  |  |  |  |  |  |  |  |  |  |
| Dec. 31, 1981 | 2 | .6 | --- | --- | 1 | 1.8 | --- | --- | --- | --- | 3 | .6 |
| Dec. 31, 1982 | 2 | .6 | --- | --- | 1 | 1.5 | --- | --- | --- | --- | 3 | .5 |
| Dec. 31, 1983 | 2 | .6 | --- | --- | 1 | 1.5 | --- | --- | --- | --- | 3 | .5 |
| Change, 2 year Period | --- |  | --- |  | --- |  | --- |  | --- |  | --- |  |
| **Native American** |  |  |  |  |  |  |  |  |  |  |  |  |
| Dec. 31, 1981 | 1 | .3 | --- | --- | --- | --- | 1 | 7.7 | --- | --- | 2 | .4 |
| Dec. 31, 1982 | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dec. 31, 1983 | 1 | .3 | --- | --- | --- | --- | --- | --- | --- | --- | 1 | .2 |
| Change, 2 year Period | --- |  | --- |  | --- |  | - 1 |  | --- |  | - 1 |  |

| Categories, Minority and Total | Public Health Service | | Health Care Financing Admin. | | Social Security Admin. | | Human Development Services | | Office of the Secretary | | Department of Health and Human Services, Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | No. | % | No. | % | No. | % |
| **Asian American** | | | | | | | | | | | | |
| Dec. 31, 1981 | 5 | 1.4 | --- | --- | --- | --- | 1 | 7.7 | --- | --- | 6 | 1.1 |
| Dec. 31, 1982 | 5 | 1.5 | 1 | 2.6 | --- | --- | 2 | 16.7 | --- | --- | 8 | 1.4 |
| Dec. 31, 1983 | 5 | 1.5 | 2 | 5.0 | 1 | 1.5 | 2 | 18.2 | --- | --- | 10 | 1.8 |
| Change, 2 year Period | --- | | + 2 | | + 1 | | + 1 | | --- | | + 4 | |
| **Total, Minority Categories** | | | | | | | | | | | | |
| Dec. 31, 1981 | 64 | 18.5 | 8 | 21.1 | 18 | 32.1 | 7 | 53.8 | 22 | 27.8 | 119 | 22.3 |
| Dec. 31, 1982 | 59 | 17.9 | 9 | 23.1 | 24 | 36.4 | 7 | 58.3 | 25 | 27.5 | 130 | 24.2 |
| Dec. 31, 1983 | 65 | 19.4 | 13 | 32.5 | 25 | 36.8 | 6 | 54.5 | 26 | 29.9 | 135 | 24.9 |
| Change, 2 year Period | + 1 | | + 5 | | + 7 | | - 1 | | + 4 | | +16 | |
| **Total, All Categories** | | | | | | | | | | | | |
| Dec. 31, 1981 | 347 | 100.0 | 38 | 100.0 | 56 | 100.0 | 13 | 100.0 | 79 | 100.0 | 533 | 100.0 |
| Dec. 31, 1982 | 330 | 100.0 | 39 | 100.0 | 66 | 100.0 | 12 | 100.0 | 91 | 100.0 | 538 | 100.0 |
| Dec. 31, 1983 | 336 | 100.0 | 40 | 100.0 | 68 | 100.0 | 11 | 100.0 | 87 | 100.0 | 542 | 100.0 |
| Change, 2 year Period | -11 | | + 2 | | +12 | | - 2 | | + 8 | | + 9 | |

### CORRESPONDENCE CONTROL

Secretary HECKLER. Absolutely.

I would like to say that we are also making a very substantial effort to engage, recruit, and promote the handicapped within the Department, because this is also a group that has been left by the wayside.

Senator PROXMIRE. I am glad you brought that issue up. I neglected that particular group, and it is very important. I appreciate the information.

Secretary Heckler, last year Mr. Sopper and I discussed the Grace Commission's criticism of the way in which your mail was being handled. The commission found it took 58 days, almost 2 months, to prepare a letter for your signature, compared to 18 days for the Department of Defense and 20 days for the Veterans Administration.

Mr. Sopper said the Department was attempting to reduce the response time to 30 days.

Can you tell us what progress you are making?

Secretary HECKLER. We are still working on the problem. One of the improvements we have introduced was not to require a finally typed product as the draft of every response. That has saved a great deal of time. The average response time at the end of the first quarter of this fiscal year was between 40 and 45 days. I think this quarter will show continued improvement. We also feel that the electronic mail system will provide much faster response time.

This is a continuing problem, but our goal is to reduce the response time to 30 days.

Senator PROXMIRE. Thank you.

One final question. I understand the position of Under Secretary of Health and Human Services has been vacant since last summer. What effect has the failure to fill that vacancy had on the Department's operations, and do you have any idea as to when someone will be nominated to fill that post?

I have an excellent candidate for the post. He is awaiting approval at the White House.

I don't believe there has been a negative impact on the Department. I would say that perhaps the negative has been the impact on me.

Senator PROXMIRE. Thank you.

Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator Proxmire.

### ICF/MR REGULATIONS

Madam Secretary, my investigation of cases of abuse of institutionalized retarded citizens has, as you know, highlighted the striking and shameful backsliding of the Department of Justice in protecting these people, these human beings.

Also, however, we have strong reason to believe that the ICF/MR quality assurance surveys do little to correct these abuses. Would you please advise me what progress your Department has made to upgrade compliance with ICF/MR regulations, particularly as they relate to programmatic as opposed to structural requirements?

Secretary HECKLER. We are definitely making very substantial inroads in this field. I share your concern and I applaud your own initiative in this field. Personally, as Secretary of HHS, I found that one of the most outrageous examples of noncompliance with our regulations occurred in my own home State of Massachusetts. We have threatened them with the loss of $34 million and possibly more. The State has appropriated the money to bring the facilities up to our standards. This has developed over a number of years. They have ignored the problem for over 10 years.

We are also inspecting, reviewing, and surveying other facilities across the country, and we are taking a hard line on the issue.

I have to say as well that the level of care in the Massachusetts facilities was superb, but that it was the physical structure that was degraded, to the point that it was just unsuitable for human habitation.

I feel strongly that we must look at both the physical environment as well as the support services for the patients. I feel this all the more strongly after having been involved in the homeless problem in America.

We have always had homeless, in fact, throughout civilization, but those who are mentally retarded and have been released from institutions without being provided adequate shelter are a real problem. While deinstitutionalization is desirable for those who have the capacity to cope in a different environment and for whom provisions are made, deinstitutionalization without appropriate followup has a significant new dimension of the homeless problem.

In terms of our new surveys, I want you to know, Senator, that we have recently conducted reviews in 22 cases, found a number of homes that needed substantial changes, and have so informed the States with threat of immediate withholding of funds. We found in one State a fire hazard that we were not going to tolerate, and the State complied and moved the patients to more suitable grounds.

We intend to protect the mentally retarded. We will be rewriting the regulations with a view toward reducing redtape but providing the essential and important backup for those who are the residents in facilities.

Senator WEICKER. It was my understanding that new regulations were developed several months ago for federally funded institutions serving mentally retarded persons under the ICF/MR Program. When will these regulations be published in the Federal Register?

Secretary HECKLER. These regulations have not come to me yet. They will be at the top of my agenda when they reach me.

## SPECIAL EDUCATION FUNDING

Senator WEICKER. One last question and then Senator Chiles can have his time. You have been very patient and kind, and we should be able to bring matters to a conclusion.

I can't help but notice one of those contradictions that seem to be commonplace in this administration, and maybe we can correct this one with a little coordination between you and the Secretary of Education.

On the one hand you and the administration are out there trying to develop Baby Doe rules to guarantee the life of children that are born with abnormalities, while at the same time the track record on special education is:

In 1983 state grant, administration budget, $672 million; appropriation, $970 million.

In 1984, $998 million, administration; $1.68 billion appropriations.

In 1985, $1.68 by the administration, and the Congress will probably up that.

Early Childhood Program: 1983, $8.4 million, administration; $16.8 million appropriation; 1984, $11.8 million, administration; $21.1 million appropriated; and $21.1 million is now the request for 1985.

The Reagan request in the special education and training of personnel is a 33-percent cut for fiscal year 1985; rehabilitation training, 78 percent cut for fiscal year 1985.

I think it is commendable as far as protecting the life of an infant that is born. Obviously the question in light of it is, what does the administration do toward what happens next?

Secretary HECKLER. Senator, obviously Secretary Bell will have to respond to this question because these are not my programs.

Senator WEICKER. You're one administration; you're out there plugging for Baby Doe rules. These are the very people that when they live and survive need this kind of help, and yet the administration is unwilling to put the dollars out to make sure that indeed there is a life after that initial phase in the hospital. I think this is just as much your problem as Secretary Bell's problem.

Secretary HECKLER. I have more than enough issues that are of major concern to me with the 250 or more programs in my Department, Senator, and I am just not able to give you a sophisticated answer on that subject.

Senator WEICKER. So in other words, what you are going to say is we want the child to live, but then I wash my hands of the responsibility.

Secretary HECKLER. No; we are doing very substantial things in our Department on the handicapped. We have a committee on the handicapped, and our initiatives will be on employment of the handicapped. Right now we have a goal this year of finding placement for 25,000 handicapped people.

Senator WEICKER. That is not what I am referring to, Madam Secretary. Let's not fog the issue.

Secretary HECKLER. I am saying this is what I am dealing with in my Department.

Senator WEICKER. You've got a high visibility publicicity issue with the Baby Doe rules. I am saying to you, if you are going to do that, then you certainly ought to be consistent as part of the same administration in assuring that those children have a chance at life.

Secretary HECKLER. I agree.

Senator WEICKER. And that is not the track record. This is the unpublicized, mundane, pick and shovel, lineman's work, if you will, in assuring that there is life for these people. That doesn't get the old television cameras. So this is the record of the administration here while it goes around on Baby Doe. I don't understand that. I really don't. You're part of the same administration. It seems to me there ought to be consistency of attitude which is a reverence for those that need our special care, not just to establish some rules and regulations and figure the devil take the hindmost after that, and that is what this record talks about. And I would hope that there would be a coordination between what you are trying to do and what Secretary Bell is trying to do, instead of just saying, well, that's his baby, that's his Department.

Senator Chiles.

Senator CHILES. Thank you, Mr. Chairman.

### REFUGEE SOCIAL SERVICES FUNDING LEVELS

Madam Secretary, you may want to get Phil Hawkes to help you with some of these questions.

Secretary HECKLER. Thank you for alerting us to your concerns, Senator, because we do want to be responsive and we want to provide the expertise that you require.

Senator CHILES. In 1983 Congress appropriated $72 million for social services to refugee entrants, $81 million targeted for impact aid. Since that program is up for reauthorization in 1984, the Congress specified current services funding for these programs for fiscal year 1984. My understanding is that your office defines the current service allocations for social services as $44 million, that $20 million would be transferred from impact aid to provide the 90 percent hold harmless that the law provides for.

How do you get the $44 million figure as covering current service? Why not say it would take $64 million to maintain current services, or even take the 1983 dollar figure of $72 million?

Mr. HAWKES. Senator, the 1983 figure was made up of two components. We had originally requested $59 million for social services based on an expected refugee admission ceiling of 90,000. Congress added $12 million to that under the continuing resolution, to make it a $72 million line item for social services. We actually received only 60,000 refugees in 1983. So we overfunded and provided more money than the number of refugees in the program would have called for.

Senator CHILES. Isn't there a processing backlog that can be made up for in 1984 when you start talking about overfunding?

Mr. HAWKES. We also issued funds specifically related to the backlog in 1983 from the $81 million in targeted assistance. We, in fact, asked States to document their backlog of unserved refugees and made additional awards during the course of the year specifically to treat those people. In 1984 we are expecting 72,000 refugees to arrive. That would have yielded a formula figure of $32 million. We added the $12 million which Congress added in 1983 and came up with a $44 million social services estimate for 1984.

Senator CHILES. Can you tell me where in the current refugee law there is any provision tying the Social Services Program eligibility to new arrivals or someone here less than three years?

Mr. HAWKES. Senator, it doesn't specifically tie it to that, although the intent of the Refugee Act is that it is a 3-year Federal responsibility. We have collected a lot of data over the past several years that show a 3-year period is adequate for most refugees.

Senator CHILES. For Mariel refugees?

Mr. HAWKES. Even most Mariel refugees are currently employed, Senator.

Senator CHILES. Currently employed?

Mr. HAWKES. Yes, sir.

Senator CHILES. You mean a lot of them are currently incarcerated.

Mr. HAWKES. Well, that's true, too.

Senator CHILES. And then as soon as they get out on the streets they have to be incarcerated again. I'd hate to have you go into Dade County and tell people down there that you can take care of the Mariel problem or it will take care of itself in 3 years, when you see all of the criminals that were dumped out there and no provision is made to the States for paying for that incarceration, no provision is made for rehabilitation efforts to try to deal with that. You are not dealing with a normal refugee situation there.

Mr. HAWKES. Senator, under the current Refugee Act, or the Refugee Act that expired the beginning of this fiscal year, there was no provision to pay for all or part of the cost of incarceration. There is currently an amendment to the reauthorization bill, as I am sure you are aware, which would allow the Attorney General to reimburse States for some of their costs associated with incarceration within available appropriations. However, Dade County specifically has a program that is aimed at entrant offenders, felons, or accused felons, which involves very heavy social services directed at that population. In fact the county requested permission to move $2 million from health assistance in Dade County last year to this particular program to deal with these entrants.

### FISCAL YEAR 1984 TARGETED ASSISTANCE

So I think we do recognize the problem and within the confines of the Refugee Act have worked with Dade County to make funds available for that population.

Senator CHILES. I like that answer, "within the confines of the Refugee Act." First you tell me there is nothing in the Refugee Act that limits you to having to take the refugees you expect for the 3 years, and then you say that you have been magnanimous and you have allowed Dade County to move some of their money from health, which they don't have enough to cover, to try to hit this entrant program. In the Impact Aid Program you plan to allocate $81 million as follows:

Five million dollars to Dade County schools; $6 million to Jackson Memorial Hospital, that is, in 1983; $40 million to the States by formula, compared to $70 million allocation in 1983; $2 million to be transferred to social services and $10 million for special projects.

I, of course, still don't see why current services is not the fiscal year 1983 level for this program, and not for social services. There should not have to be a transfer out of this program when there is up to $72 million available for social services.

What is the $10 million for special projects for? Why are you not allocating at least $50 million to the States that are heavily impacted with refugees and entrants?

Mr. HAWKES. Senator, there actually is $5 million, with the $11 million specifically for Dade County and $40 million, part of which goes to Florida. Also the $10 million in special projects will go mainly to States.

Targeted assistance, Senator, is more than just putting money into 30 or 40 areas of the country. The refugee and entrant population is a very mobile population, and they tend to follow money. So to some degree, if we fund certain areas of the country very heavily, refugees and entrants will perceive that there is refugee money and refugee services available there, and they then move to those areas. This, while on the one hand we distribute money specifically for targeted assistance, on the other, we try to create conditions in communities where refugees are residing, where the impacts are not great, to attempt to hold them there. The $10 million for special projects will be aimed specifically at that goal.

We had a situation last year in which several hundred highland Lao refugees per month were leaving areas around the country and moving to the central valley of California. It reached the point where 13 to 14 percent of the area is today made up of refugees. By making small awards to communities through State governments in several parts in the country, we were able to stabilize that. We think that it is important to keep these people from moving from areas where they are likely to have jobs and become self-sufficient to other areas where they are very likely to be on assistance and not have jobs.

So there are two parts to targeted assistance, and we walk a fine line between the two. One is to fund the areas of need and the other is to prevent additional people from moving to those areas of need.

### TARGETED ASSISTANCE FUNDING

Senator CHILES. When the Impact Aid Program was created it was designed to respond directly to the need of those counties that were suddenly hit with large and unanticipated numbers of refugees and entrants. Congress purposely made the program flexible to meet the full range of job training, health, social services, and law enforcement needs of the areas. Now it looks like your thrust is getting more and more narrow and the impact aid is a job training program. I don't know how you justify this. If you go down to Dade County or out to California or Oregon you're going to see a lot of needs in those counties before they ever think about training people for jobs. Jackson Memorial Hospital in Miami is flooded with indigent Haitians, and now El Salvadorans and a lot of people from Central America. We know that we had the prisoners that came to us via Mariel, which makes Dade County's law enforcement needs still tremendous.

What is Congress going to have to do to get the Impact Aid Program back on a flexible problem solving basis rather than have it narrowly restricted to job training.

Mr. HAWKES. Senator, I don't think it is narrowly restricted. As you just stated, we are giving $5 million to Dade County schools and $6 million to Dade County health. We do insist that the thrust of the money go toward job development or job development related expenses. That can be child care; that can be transportation to and from work; and it can be mental health care which makes a person capable of holding a job. The whole range of title 20 related services is included under targeted assistance. We have been very liberal, I think, in our interpretation. However, the figures that have been supplied to us by Dade County include many populations or refer to populations who are not refugees or entrants. The Nicaraguans whom you mentioned, and the Salvadorans and others, are not reachable under the Refugee Act. While that does certainly impose a burden on Dade County, and specifically on Jackson Memorial Hospital, we can't use ORR funds to take care of that.

### ORR FUNDING TO FLORIDA

Senator CHILES. Then the overall thrust of it is that the Federal part of taking up the slack for the local and State government that they have incurred has been still a small percentage of what that occurrence has been. And when you see local governments sort of overwhelmed, like Dade County, Jackson Memorial being the charitable hospital, sort of, of Dade County and the amount of time of that, it seems we should change the thrust of the program and allow the utmost flexibility to the local governments to use those few dollars that we are giving them. It was not Dade County that said we are opening our doors to refugees; that was a Federal decision or the absence of a Federal decision, and it should be a Federal responsibility.

Mr. HAWKES. Senator, since the Mariel boatlift, the Federal Government, through our programs, has awarded about $450 million to the State of Florida. In several cases we have worked with the State to allow unexpended funds to be carried over because the State was not able to obligate the money or contract for services. We will continue to work with the State and Dade County specifically in an effort to create the degree of flexibility that they need to work with this population within the intent and the direction of the Refugee Act. It is my intention to continue discussions with the State of Florida.

Senator CHILES. Thank you, Mr. Chairman.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions which I will submit along with any other Senators.

Senator Proxmire.

Senator PROXMIRE. No questions.

Senator WEICKER. Madam Secretary, we thank you for your patience and we very much appreciate your testimony.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### MANAGEMENT STYLE

Question: Madame Secretary, you no doubt saw a recent Wall St. Journal article in which someone described you as a "human whirlwind who's surrounded by confusion." There were references to leadership by groping and a lack of communication between your office and the rest of the Department. We fully recognize that HHS is a tough agency to manage, but it would be helpful to know what steps you are taking to allay such concerns about the how the Department in being run, or not run.

Answer: I would be the first one to admit that, in a Department the size of HHS, we can always take action to manage better and we are always open to innovative ideas. However, I would not agree with the thrust of your question. First of all, there is no problem that I am aware of in communicating my goals and priorities to departmental leadership and in securing their own ideas and responses. In addition to my weekly "senior" staff meeting with all Heads of Operating and Staff Divisions, I meet often with these and other top departmental managers on specific issues and problems. In these meetings and through memoranda, we freely communicate our ideas.

I have also taken many actions to strengthen management and operation of the Department. The Department is vigorously applying the principles of the Administration's Reform '88 initiative to its operations. I detailed some of these for you in my opening statement including gains in collection of debt owed the Department, strong support for the Inspector General's efforts to fight fraud, abuse and waste, further reductions in paperwork burden, and many others. I have used recommendations of the Grace Commission to streamline overhead functions and staff, especially in the Office of the Secretary. I strongly encourage the progress of the Social Security Administration's Systems Modernization Plan which will achieve improved service to beneficiaries combined with major savings in Federal staff. I have moved firmly to rationalize and humanize the continuing disability review process. I have strongly supported research into emerging new health problems such as AIDS and Alzhemier's disease. The list is quite long.

### DEPARTMENTAL MANAGEMENT VACANCIES

Question: We understand you still do not have a new Under Secretary on board and you are about to lose several top managers. There may be other important vacancies. What are you doing to speed the filling of vacancies among top management?

Answer: I have in mind a candidate for the post of Under Secretary and I am hopeful that it will be filled shortly. The nomination of John Scruggs as the Assistant Secretary for Legislation is awaiting Senate floor action. We are moving quickly to fill other vacant posts as we find qualified people to fill them.

### ASSISTANCE TO THE APPROPRIATIONS COMMITTEES

Question: As we near Subcommittee mark-up, we often need information from your budget office within hours on the effect of proposed Senators' amendments. Will we still get timely "Effect of

Senator's Amendment" packages to help us prepare for Subcommittee mark-up?

Answer: The Subcommittee will continue to receive the Effect of Amendment packages and other materials traditionally provided to it by the budget office. My staff and yours have discussed this matter, and we see no barriers to providing timely and effective assistance to the Subcommittee.

## DELAY IN STREAMLINING PLANS

Question: It is my understanding that in August of 1983 you signed a memorandum to your Office Heads notifying them that there would be a restructuring of the Office of the Secretary including a reduction in the workforce. You further stated that your Chief of Staff, George Siguler, would communicate the specific elements of the plan within a few days.

Yet, Mr. Siguler did not communicate any details until March 19, 1984.

In the meantime the Executive Board of Local 41 of the AFGE wrote you an open letter complaining that the only information available about these proposed changes was from newspaper accounts.

Why did it take seven months to relay the specifics of this plan to your staff?

Answer: Last August I approved the conceptual framework of the plan that was announced on March 19.

Developing the details of a reduction plan of the magnitude of a 1,264 staff decrease is extremely complex and time-consuming. For example, staffing levels in the Office of the Secretary affect the Department's Operating Divisions, and we were very careful to ensure that staff reductions in OS did not place workloads on the OPDIVs that they could not manage.

In addition, I wanted a plan that held the loss of jobs for current employes to an absolute minimum. I think that the course we are pursuing does just that. Of the 1,264 staffing reduction, nearly three-fourths would be reduced by attrition and transfers of OS staff to the Operating Divisions, leaving only about one-fourth to be reduced by early out retirements, outplacements and involuntary separations as a last resort.

In summary, the three principal factors that I wanted embodied in this plan were assurances that:

- o critical workloads will continue to be met;
- o centralized services will continue without interruption;
- o adverse personnel actions will be minimized.

While I regret any inconvenience the delay may have caused in the short term, I believe that the March 19 plan is fair and practical and will allow the Department to operate more efficiently over the long term.

## NIH OVERVIEW

Question: I am sure you are aware that a major priority of the Congress has been to maintain the momentum of research at NIH. Why does your budget provide only about a 2 percent increase over fiscal 1984 for NIH while OMB is projecting fiscal 1985 inflation to be about 4.7 percent?

Answer: Decisions on the level of support for NIH were made on a priority basis among the different types of support mechanisms. While the +$89 million increase requested for NIH is a 2 percent increase overall, we have provided for a 5 percent average cost increase for our highest priority, research project grants, which will total $2.5 billion in 1985. Furthermore, within research project grants, certain areas of highest priority will receive an even greater increase than 5 percent. For example, grants funded by NIAID, including important AIDS research, will receive a 9 percent average cost increase.

In 1985, $2.5 billion is requested to support 5,000 new and competing research project grants, an increase of $103 million above 1984. This will allow NIH to support a historically high level of over 17,000 total research project grants for the second year in a row. This is especially significant in view of the important contributions made to the advancement of biomedical research through this investigator mode of research.

All other research mechanisms, such as research centers, contracts, disease control awards, and intramural research will be maintained at essentially the same dollar level as in 1984; that is, approximately $1.8 million. In addition, based on scientific priorities, some Institutes will fund discreet projects intramurally or through the Research Project Grant mechanism, rather than through a variety of other mechanisms as in the past. For example, NIAID will fund vaccine development in the Intramural program, rather than through the R&D contract mechanism.

In developing this budget request, our number one concern was the support of 5,000 new and competing research project grants including an aggregate 5.0 percent increase per award. Beyond that, sufficient flexibility was provided to individual Institute Directors to direct the remaining resources toward those areas, and by the most appropriate mechanism, which were considered scientifically most opportune.

I am confident that this budget will continue our leadership in biomedical research, leadership which is vital to insure long-term improvements to our Nation's health. The Federal investment in biomedical research, which has more than doubled since 1975, continues to dramatically advance our understanding of disease, disease processes, treatment, and prevention. For example, NIH grantees have recently located the gene responsible for Huntington's disease. Aside from the major implications this discovery has for those afflicted with, or carrying, this trait, it also is significant because it demonstrates how the techniques of basic molecules biology can be used to attack a disease whose biochemistry is unclear and for which there is no cure. In addition, there has been progress in identifying the causative agent for Acquired Immune Deficiency Syndrome (AIDS), the number one health priority of my Department. We recently announced these findings, following confirmatory investigations. This identification will help us to diagnose those with AIDS, aid in blood screening, and allow us to further describe the natural history of the disease. It could also provide the impetus to start looking at vaccine development to eventually prevent the disease. Finally, it is important to note that progress in cancer research is continuing, and the survival rate for those with cancer is now thought to be at least 50 percent. Cancer deaths among children were reduced by half in the period 1965-79 and more gains are expected.

Question: What impact will you low budget have on the ability of NIH to take advantage of the scientific opportunities that are becoming available?

Answer: The NIH request will allow biomedical research to continue to advance at its current pace. The request will support over 17,000 total research project grants for the second year in a row. This level is the highest in the history of NIH.

All other research mechanisms will be maintained at essentially the same dollar level as in 1984. Because of the award cycle of NIH extramural awards there is a constant ebb and flow as new projects are initiated while others are concluded. As such, there will be the initiation of a substantial number of new projects supported by our request.

It is important to note that the average size of research project grants has risen rapidly in recent years, far out-stripping most standard indices used to measure the economy. Increases in the average size of research project grants has compared with various economic indices as follows:

| | Percent Increase | | |
|---|---|---|---|
| | 1979-1985 | 1983-1985 | 1984-1985 |
| Average size, new and competing. | +63.0% | +20.5% | +5.0% |
| Average size, noncompeting...... | +56.5% | +15.3% | +5.0% |
| BRDPI*........................ | +48.5% | + 9.8% | +4.5% |
| GNP Deflator.................. | +46.3% | + 9.4% | +4.9% |
| CPI........................... | +52.0% | + 8.7% | +4.5% |

* Biomedical Research and Development Price Index

Question: Isn't it true that under your budget the average amounts made available for new grants will fall about $9,200, or about 6 percent below study section recommendations -- and the average amount made available for continuations will fall about $8,300, or 5.4 percent below your commitment level?

Answer: We feel that a 5 percent increase in the average cost of research project grants is adequate. Some downward negotiations will have to occur, but this is not a unique situation, and we do not believe that the quality of research will be adversely affected.

Historically, NIH has always negotiated the direct cost of grants downward, even in the absence of budget constraints. In the most recent years, these have averaged 3 to 4 percent for new and competing grants and 1 percent for noncompeting grants.

Despite initial estimates by the Institutes of 5 to 6 percent aggregate downward negotiations, most Institutes do not have a policy of across-the-board downward negotiations; rather, the most meritorious grants are fully funded, while others may receive more substantial reductions.

Question: Isn't it also true that your budget request for research centers and other research activities actually will be almost $2 million below the fiscal 1984 level ($670 million vs. $668 million)? Won't such a level budget in this area reduce NIH's ability to translate research results into prevention and treatment?

Answer: We feel that these other research endeavors will not be compromised. Within this level of funding, efficiencies can be achieved to compensate for the effects of inflation. We believe that individual scientists and science administrators are best able to develop the means to become more efficient. For example, certain trade-offs might be made between travel vs. supplies or whether a less expensive, but equally capable, piece of equipment could be substituted for a "top-of-the-line" model.

Within this overall spending level for the other research mechanisms, the Institute Directors have allocated resources to address their highest research priorities. Furthermore, some Institutes will fund discreet projects intramurally or through the research project grant mechanisms, rather than through a variety of other mechansims, as in the past. For example, NIAID will fund vaccine development in the Intramural program where the world's most renown vaccine development expertise exists, rather than through the R&D contract mechanism.

Question: How much additional money above your request would it take to fund NIH's fiscal 1984 level of effort in fiscal 1985?

Answer: The following table indicates the additional amounts that would be necessary and the related assumptions to fund the same level of extramural and intramural effort as in 1984. You should note, however, that current services for NIH in 1985, based on the 1984 appropriation, is $4,679,554,000. This calculation assumes a 5.4 percent increase for all non-pay related items except for General Clinical Research Centers, which are provided a 6.1 percent increase. This represents an increase of $113.1 million over the request, rather than the $269.9 million shown below.

(Dollars in millions)

| | |
|---|---|
| Research Project Grants* | |
| Noncompeting | $83.9 |
| Administrative Supplementals | 1.3 |
| Competing | 64.9 |
| Centers | 23.0 |
| Other Research | 12.5 |
| Subtotal | 185.6 |
| Training** | 16.0 |
| Research Contracts | 21.4 |
| Intramural Research | 17.2 |
| Other*** | 29.7 |
| Total, NIH | $269.9 |

* Reflects 5,272 new and competing grants, the same number as 1984; includes a 8 percent increase for new and competing grants and a 10 percent increase for non-competing grants consistent with NIH cost model projections of future costs and assumes the same percentage of funding as was accomplished in 1984, i.e., approximately 97 percent of projected full costs for new and competing grants and approximately 99 percent of projected full costs for noncompeting grants.

** Reflects 9,863 trainees, the same number as in 1984 funded at the 1985 average cost (which includes a 5 percent stipend increase over 1984).

*** Includes current services funding in research management and support, disease control, construction, the National Library of Medicine, the Office of the Director, and Buildings and Facilities.

Question: In a speech last November, Dr. Wyngaarden pointed out the importance of bringing the research effort up-to-date by replacing obsolete instruments and deteriorating extramural laboratories and facilities. I'm sure you are aware of this, and we would like to know if you have any plan to deal with these problems?

Answer: Regarding instrumentation, in recent years the NIH has been increasing its support for instrumentation through several different mechanisms. To support the needs of research projects in areas of interest to the National Institute of General Medical Sciences, that Institute awards supplemental funds to provide shared instrumentation. The Biotechnology Research Program of the Division of Research Resources provides support to assure the development and availability of high technology instruments, to be shared on a regional or national basis. Shared instrumentation grants provide for state-of-the-art equipment to be shared within Institutes. The Minority Biomedical Research Support grantees receive shared instrumentation through supplemental funding. Research project grants provide for relatively inexpensive equipment that does not lend itself to shared usage. Funding for the various instrumentation programs, as well as estimates for equipment provided through research grants, are shown below:

Instrumentation Programs
(dollars in thousands)

| | 1983 Actual | 1984 Estimate | 1985 Estimate |
|---|---|---|---|
| General Medical Science.......... | $671 | $255 | $255 |
| Division of Research Resources: | | | |
| Biotechnology Research......... | 20,204 | 27,393 | 27,677 |
| Shared Instrumentation Grants.. | 14,000 | 19,770 | 19,770 |
| Minority Biomedical Research Support...................... | 1,000 | 1,000 | 1,000 |
| Subtotal, DRR............. | 35,204 | 48,163 | 48,447 |
| Total, NIH............... | $35,875 | $48,418 | $48,702 |

Equipment Provided by Research Grants
(dollars in thousands)

| | 1983 Estimate | 1984 Estimate | 1985 Estimate |
|---|---|---|---|
| Total, NIH.... | $45,500 | $51,700 | $54,000 |

With regard to future instrumentation needs, we are cooperating with the National Science Foundation in a study of these requirements. This study is expected to be completed and available by April 1985.

As far as facilities are concerned, the NIH Office of Program Planning and Evaluation last year conducted an analysis of the NIH experience with the use of construction authority for non-Federal health research facilities. The objective of the assessment was to analyze past experience rather than to recommend future courses of action. However, it did become obvious from the assessment that no comprehensive survey of health facilities construction has been done since 1968.

Subsequent to the completion of the report, it was discovered that two other agencies (the Department of Defense and the National Science Foundation) had been asked by the Congress to examine the state of university research facilities. We have now joined with the Department of Defense, the National Science Foundation, the National Aeronautics and Space Administration, the Department of Agriculture, and the Department of Energy to plan a major survey covering all engineering, scientific, and medical research facilities at academic and nonprofit institutions.

Question: Your NIH justification recognizes that it takes a long time to develop outstanding researchers and that "the level of training supported today determines our research capability in the future." In view of that statement, why are you proposing to reduce NIH training slots from 9,863 in FY 1984 to just 9,000 in the coming fiscal year?

Answer: In allocating available resources among many competing priorities, some very difficult decisions had to be made. The highest priority for NIH was placed on supporting 5,000 new and competing research project grants. All other mechanisms, including training, were held at essentially the 1984 dollar level. Furthermore, on training, we felt that it was important to provide a 5 percent stipend increase since it had been several years since it had been raised. Within the context of this budget, I believe that support for 9,000 trainees is appropriate and sufficient to assure that our future research capability will not be seriously damaged.

## MATERNAL AND CHILD HEALTH BLOCK GRANTS

Question: The Subcommittee is deeply concerned about Administration efforts to change the Maternal and Child Health Block Grant.

- o You are proposing that Congress eliminate the 15 percent set-aside for projects of regional and national significance, and provide for the money to be routinely distributed back to the States. Isn't this effort to knock out the sensitive research and training projects under the set-aside simply a means to project some semblance of a current services budget for the Block?
- o You've tried this approach before and Congress didn't bite. What makes you think things are different up here this year and we'd go for removing the set-aside (about $61 million in FY 1985)?

Answer: The Administration has consistently advocated that set-asides and earmarks are not compatible with the basic concept of a block grant funding approach. Federal block grant funds are best utilized by the States in accord with their own needs assessments and resource allocations processes. The legislative proposals by the Administration would permit the entire Maternal and Child Health block grant appropriation to be allocated to the States. It is not our intent to halt various research and training activities, but instead permit the States to become involved in determining what type of studies or training is most responsive to their requirements. While we realize this legislative proposal has not received favorable consideration by the Congress in the past, the Administration continues to believe it is a sound measure.

## BATTLE AGAINST AIDS

Question: All of us continue to be concerned about the problem of Acquired Immune Deficiency Syndrome, better known as AIDS. What can you tell us about the research and control effort against this terrible disease (AIDS) and the progress you hope to make in the balance of 1984 and in the new fiscal year?

Answer: We anticipate that sufficient evidence will be accumulated over the next few months to strongly implicate one virus as the primary etiologic agent of AIDS. If these findings prove to be correct, urgent questions can then be answered. Information will be needed on the pathogenesis of the disease, the possible contribution of other agents, and the nature and the natural history of the virus. The identification of an etiologic agent should make it possible to develop specific diagnostic tests for AIDS, to identify potential transmitters, and to improve screening procedures for blood and blood products. Ongoing epidemiologic investigations, studies under development, and those based upon these specific test could further define the modes of AIDS transmission and lead to implementation of strategies to interrupt and control the disease. The isolation of a viral agent is also likely to result in additional human isolates of previously unidentified retroviruses whose role in diseases other than AIDS must be specifically delineated.

In close cooperation with State and local health departments, national and community organizations, PHS will continue to disseminate information on AIDS and its prevention to public health and medical professionals, risk groups, and the general public. As the result of isolation of the viral agent, development of a vaccine will be initiated as well as appropriate treatment of people with AIDS.

## BATTLE AGAINST AIDS, ALZHEIMER'S

Question: We note that you are projecting a department-wide budget of about $54 million for AIDS. This is an increase of slightly more than $6 million over fiscal 1984. To what extent will this budget be sufficient to help you meet your objectives in the battle against AIDS?

Answer: We believe the money we have requested for AIDS is sufficient. Dr. Brandt is constantly assessing the research needs and funding situations for AIDS. If we determine that additional funds are necessary, we will be back to you.

(Dollars in thousands)

| | FY 1982 | FY 1983 | FY 1984 | FY 1985 |
|---|---|---|---|---|
| CDC.......... | $2,050 | $6,202 | $12,000 | $12,020 |
| NIH.......... | 3,355 | 21,668 | 34,159 | 40,316 |
| FDA.......... | 150 | 350 | 400 | 475 |
| ADAMHA....... | --- | 464 | 1,036 | 1,281 |
| PHS, Total... | $5,555 | $28,684 | $47,595 | $54,092 |

Question: Another major priority of the Congress is the effort to make some progress against Alzheimer's disease. It thus is with some concern that we note your budget proposes to increase Public Health Service funding for Alzheimer's by only about $1.4 million in fiscal 1985. Why so little?

Answer: Although the 1985 level of $38.6 million, an increase of $1.5 million, does not represent a major increase over the current year, it is important to note that the Public Health Service funding for Alzheimer's has increased dramatically in recent years. For example, in 1979 we funded $9.7 million in this area; by 1981 the figure had grown to $16.7 million, and in 1983 we obligated $27.1 million.

I believe that the President's budget, with its many competing demands, is allocating an appropriate share of resources to research on Alzheimer's disease. However, as more investigators become interested in this field, and as the knowledge base continues to expaand, a higher level of research activity may become essential to take advantage of scientific opportunity.

## ICF/MR COMPLIANCE WITH REGULATIONS

Question: My investigation of cases of abuse of institutionalized retarded citizens has, as you know, highlighted the striking and shameful backsliding of the Department of Justice in protecting these citizens.

Also, however, we have strong reason to believe that the ICF/MR quality assurance surveys do little to correct these abuses. Would you please advise me what progress your Department has made to upgrade compliance with ICF/MR regulations, particularly as they relate to programmatic as opposed to structural requirements?

(Examples of lack of programming include one or two hours of schooling per day, no communication training for deaf clients, no mobility training for blind clients, no training in basic life skills like food preparation; medication used instead of teaching appropriate behaviors.)

Answer: The Department has been involved in the following efforts to upgrade compliance with ICF/MR regulations:

- We have taken disallowances in three States in the last two years based on our judgment that the facilities involved were not providing minimally adequate active treatment to clients.
- We are currently completing a series of direct Federal surveys of public ICFs/MR in 11 States. We terminated the participation of one facility based upon life threatening conditions identified. After we review the findings in other facilities, we will decide what Federal actions, if any, are appropriate.
- We have improved our training of surveyors to enable them to make better, more defensible judgments about the quality of services to clients in ICFs/MR.
- We are currently studying ways to strengthen our program of utilization control to ensure that clients are appropriately classified for the ICF/MR level of care and that each client is receiving needed services.

Taken together, these efforts clearly demonstrate that we will not tolerate less than aggressive, thorough, and consistent enforcement of quality standards for ICFs/MR.

## NEW ICF/MR REGULATIONS

Question: I understand that new regulations were developed several months ago for Federally funded institutions serving mentally retarded persons under the ICF/MR program. When will these regulations be published in the Federal Register?

Answer: The Health Care Financing Administration (HCFA) has developed draft regulations for intermediate care facilities for the mentally retarded (ICFs/MR) which have undergone review and comment within that agency. The modifications have been undertaken to simplify the existing requirements for these facilities and to increase the focus of attention on the provision of necessary active treatment to each developmentally disabled client. The draft regulations are expected to be submitted to other components of the Department of Health and Human Services for review and comment prior to publication in the Federal Register. Although I cannot provide you with an exact date, since they are still under review, we do expect that an NPRM will be published sometime in FY 1985.

Question: Given the overwhelming and accumulating body of evidence that supports services to retarded persons in family size settings as a cost effective and programmatic effective alternative to institutional care, why has not your Department developed legislative proposal to allow some shift of ICF/MR dollars from institutions to community settings?

Answer: The Department does not yet have conclusive evidence concerning the programmatic or cost effectiveness of community-based alternatives to Medicaid ICF/MR care for mentally retarded Medicaid clients.

A growing amount of Medicaid ICF/MR care has already been shifted from large institutions to smaller community units. Of the approximately 2,100 Medicaid-certified ICFs/MR, about 1,370 are now facilities with 15 or fewer beds. Professionals, however, disagree on whether the most profoundly retarded individuals, many of whom require specialized equipment and staff to survive, can best be cared for in community settings. In addition, much of the literature comparing the cost effectiveness of small versus large care settings has tended to focus on those segments of the retarded population who require less assistance than those who remain in larger institutions.

We are hopeful that some of the Department's current activities in the area of Medicaid home and community-based care will contribute to a framework of solid data that will enable us to better assess these issues. Thirty States are now providing community-based services under 34 waivers to about 15,700 mentally retarded individuals under the Administration-sponsored Medicaid home and community-based waiver authority enacted by Section 2176 of the Omnibus Reconciliation Act of 1981. Another 18 waiver requests from ten States are pending. These waiver programs are offering a variety of services -- some not otherwise covered under Medicaid -- to recipients who otherwise would require skilled nursing or intermediate (including ICF/MR) care. A number of these waivers are specifically geared to enabling families of severely disabled children to maintain them in their own homes. Others are concerned with speeding deinstitutionalization, which has been underway in some States for some time. The most popular services provided under approved waiver programs for the mentally retarded are case management, habilitation, respite care, and adult day health services.

We have been very encouraged by the initial response to this Medicaid waiver authority. States appear to be using it to develop alternatives to institutionalization in a careful, incremental manner.

Most of these waiver programs for the mentally retarded, however, are still in their initial stages of operation. We have no definitive evaluative information on the quality of the care provided and can only project data on any cost savings to the Medicaid program. In September 1983, HCFA initiated a three-year evaluation study of the home and community-based waiver program. The project will produce annual interim reports, the first of which is expected late in 1984. We look forward to sharing the findings of this study with the Congress and public as soon as they are available.

In the absence of solid evidence of the success of our initial Medicaid program efforts in providing community-based care for the mentally retarded, we believe it is critically important that we examine the data on quality and cost from our waiver programs before entering into new benefit programs or major modifications to existing programs.

## ICFs/MR FACILITY UPGRADE

Question: How much ICF/MR money (State and local) has been used to upgrade larger facilities in the last year?

Answer: While this data is not accumulated either in HCFA or by the National Association of State Mental Retardation Program Directors, it is reasonable to assume that the sum was nominal for several reasons.

First, over $1 billion was spent on capital improvements to large institutions between 1977 and 1980 to make them compliant with ICF/MR standards. Most of this work has long since been completed and only a few States are currently engaged in large scale capital improvement programs (e.g., Massachusetts and New Jersey) to upgrade public institutions for the mentally retarded.

Second, the downward trend in average daily census at the large institutions continues (at about 115,000 today). Rather than continuing investment in the growth of institutions, most States are closing buildings, and in many instances, whole facilities, as more community programs develop.

Further, many States are subject to court decrees that limit the number of institutional beds that can be retained for use by the State. These decrees usually call for increased deinstitutionalization.

Finally, most States continue to feel the constraints imposed by the recent recession resulting in cancelled or delayed capital spending.

Question: How many group homes of 15 or fewer would have been established had the funds in (the question) above been used for group home development?

Answer: Since we do not know how much money was appropriated or expended for capital improvements in large institutions, we cannot estimate how many group homes could have been developed.

In any event, Medicaid does not provide start up funds for the development of Medicaid facilities. Many States have special loan funds for the development of group homes. There are now well over 6,000 group homes, 1,300 of which are ICFs/MR. Building a new group home can cost as much as $150-200,000. Renovation of an existing home can cost $50,000 on top of the cost of purchasing a home. It is generally viewed as more expensive to build a "bed" in the group home mode than in an institutional mode mainly because of land, development, and other costs as well as the building costs for a total unit serving a relatively small number of people.

## SOCIAL HMO DEMONSTRATION

Question: The Subcommittee is interested in your so-called "Social-HMO" experiment which would permit Medicare beneficiaries to sign up with HMOs for a group health insurance program that also provided a wide range of social services. According to a recent story in the Washington Post, OMB apparently is holding up the effort through its authority to approve certain forms that would be needed. What's going on?

Answer: An article appearing in the Washington Post on March 25, 1984 concerning the Social Health Maintenance Organization (HMO) demonstration stated that, "although OMB cannot block HHS from granting waivers and awarding contracts for the project, under the Paperwork Reduction Act it does have to approve certain forms the experiment will use before the demonstration can proceed."

As required by the Paperwork Reduction Act, the Department submitted a Request for Proposals (RFP) to OMB for Forms Preclearance Review on August 11, 1983. The RFP involved the development of the evaluation component of the Social HMO demonstration. This component is essential in order to gain sufficient information to determine the successfulness of the demonstration. Forms preclearance was denied by OMB on November 8, 1983, because they had certain problems with the project's design.

We are now attempting to relieve OMB's concerns and proceed with their approval.

Question: What efforts are you making with OMB to get the project cleared for implementation?

Answer: The Department and OMB are now discussing the project in an attempt to resolve the concerns OMB has raised. We expect to have these issues resolved shortly.

Question: Is it true that there would be no additional cost to the government and that there actually might be some saving? Are there any financial risks to the government in the proposed undertaking?

Answer: Financing for the services provided by the proposed Social HMO sites will come from a combination of Medicare and Medicaid funds as well as from private premiums, coinsurance and deductibles. The reimbursement system was designed to be budget neutral with respect to the fee-for-service sector. The Medicare program will be reimbursing at 100 percent of the Adjusted Average Per Capita Cost (AAPCC) amount as determined for the locality of each site. The Medicaid program will be reimbursing at rates determined by the respective States to be the same as the cost under the fee-for-service system. There is a chance for potential savings to the State and Federal governments through savings to the Medicaid program from delayed Medicaid eligibility of Social HMO enrollees who enter nursing homes. In total, we are not yet sure whether this would result in costs or savings.

Since the Social HMO model is a major departure from other HMO demonstrations in that there is insufficient data about costs, selection risk, and provider performance to support truly reliable initial cost estimates, the current design of the project would permit risk sharing by the government with the understanding that by the third year of the demonstration all sites will be at full risk. In most sites, the risk sharing distribution would be based on the percent contribution by the various payers (Medicare, Medicaid and private) toward the Social HMO budget. The Social HMO entity will be at risk for the proportion composed of private enrollee payments up to a site-specific stop loss amount.

## BLOCK GRANTS

Question: For the third year in a row you are proposing legislation to move the health block grants from their home agencies into the Office of the Assistant Secretary for Health. Congress has given you no encouragement to believe it would ever pass such legislation. What makes you think anything has changed up here on the Hill that would produce the transfer you seek?

Answer: We continue to believe that our proposal is reasonable. Consolidation of the administration of the block grants in a single agency will give States a single focal point for resolving any problems that arise in block grant management and will realize additional Federal efficiencies.

For three of these grants, the transitional period is complete and they are fully operational. The fourth grant, primary care, will be in a transitional year in 1985. In addition, States have developed administrative systems for the operation of block grants and now require minimal Federal assistance.

The consolidation will affect only the administrative functions related to reviewing grant applications, distributing funds according to formula, and reviewing State reports. Technical assistance required by the States would still be provided by the appropriate PHS agency.

Question: I'm frankly disturbed at what you're trying to do to the Health Resources and Services Administration. You propose to reduce its budget from $1.4 billion to $272 million by transferring its block grants elsewhere, making about $200 million in program cuts and reducing staff positions by about 1,200. If your proposals were to be accepted, what would happen to this premier Public Health Service Agency?

Answer: We expect the Health Services and Resources and Services Administration (HRSA) to remain a viable PHS organization, with continuing responsibilities for programs such as the National Health Service Corps, Hansen's Disease services, health professions education and loan activities, and the Indian Health Service, a very significant responsibility involving resources of nearly $750 million.

## FAMILY PLANNING

Question: In fiscal 1984 Congress made it clear that it wanted the Family Planning Program administered under the Health Resources and Services Administration. Why have you not complied with this directive -- why do you persist in thwarting the will and intent of Congress?

Answer: We are fully aware of, and have given serious consideration to, the desires expressed in reports of the House and Senate appropriations committees on P.L. 98-139, the Departments's FY 1984 appropriations act. Nevertheless, we strongly believe we should continue the present organizational arrangement of family planning. It is working well and is necessary to maintain a strong, high quality family planning program.

The transfer of the Family Planning Program to the Office of Population Affairs in the OASH consolidated management of the Adolescent Family Life, Population Affairs, and Family Planning programs. It eliminated the split between the setting of overall policy and the operations which implement the policy, and has improved management efficiency and coordination by providing consistency and by minimizing administrative costs.

Furthermore, the current delegation of authority has brought the Family Planning Program organizational placement into conformity with the Title X statutory provisions regarding the responsibility of the Deputy Assistant Secretary for Populations Affairs (DASPA) for administering family planning programs. The Title X legislation directs that the DASPA shall "administer all Federal laws for which the Secretary has administrative responsibility which provide for or authorize the making of grants and contracts related to population research and family planning programs."

Question: Congress provided almost $16 million more for family planning in fiscal 1984 than in the previous fiscal year. Yet we are hearing that some of our regions -- including my own Region I -- initially get less money than in 1983 because you are setting aside money in each region for "National Priorities" programs. What are these "National Priorities" and how much are you shifting from each region for this program?

Answer: In FY 1984, $5 million was distributed in equal $500,000 amounts to each of the ten regions for special projects of national priority, including natural family planning, infertility, and family involvement. None of these priorities is a new concept, and almost all are mentioned in the statute.

Historically, the Family Planning program has not provided an across-the-board funding increase for each grantee each year, based on the increase in the total appropriation. When Title X funds increased by 13.7 percent from FY 1980 to FY 1981, the proportional increases received by the regions ranged from 9.37 percent to 18.28 percent. In FY 1982, when the Title X appropriation was reduced by 22 percent in total, the regional reductions ranged from -4.8 percent to -31.9 percent.

In addition to the set-aside for special projects of national priority, the initial regional allocations for family planning grants in 1984 also vary from the 1983 levels because this year, the funds are being allocated on a new three-part analytically objective formula that considers the differences among regions regarding need, performance and the prior year's allocation. This formula provided that:

- Twenty percent (20%) was prorated to the regions based on the number of poor women-in-need of family planning services in each region.
- Thirty percent (30%) to the regions based on performance, the number, the number of women below 150% of the poverty level actually served at the regions' grantee clinics compared to the national total.
- Fifty percent (50%) was a funding stability allotment based on the amount each region received in prior years.

In 1984, Region I received a smaller increase, in part due to the fact that its share of women-in-need has dropped from 5.15 percent in the FY 1982 formula to 4.59 percent in the FY 1984 formula. Women-in-need served declined from 5.22 percent in the FY 1982 formula to 4.81 percent in the FY 1984 formula.

Question: Why couldn't you have distributed the money normally and asked each area to do some work on the so-called National Priorities? In this way, no region would have had to take what amounts to a cut in the face of an overall program increase.

Answer: Special projects of national priority have been designated in the past and have focused on some of the basic services that are cited in the Title X legislation. Prior to the designation of the national priority areas for 1984, meetings were held with grantees in each of the regions so that they could provide input as to which of the family planning services needed to be strengthened. The consensus that came from these meetings was the basis for the designation of natural family planning, infertility, and family involvement as special projects of national priority.

We believe that the $5 million allotment is a modest sum that will permit grantees in each region a certain degree of flexibility to develop ideas which would otherwise be without resources.

## MORATORIUM ON TRIMMING DISABILITY ROLLS

Question: On Wednesday, Social Security Commissioner Martha McSteen indicated she could not confirm press reports that you are preparing to announce a moratorium on trimming Social Security Disability rolls. What can you tell us at this time about your plans with respect to handling Social Security disability cases? When do you expect to give Congress details of your new plans in this area, including cost implications?

Answer: On April 13, 1984 I ordered a suspension of periodic reviews of continuing disability until Congress completes action of pending disability legislation and that legislation is implemented. Also, those individuals (reviewed under the periodic review requirement) whose claims are now pending at all levels of administrative appeal will have their benefits continued. The cost of the initiative will depend on how long the moratorium is in effect, and this information is not currently known.

A copy of the press release announcing these initiatives follows.

FOR IMMEDIATE RELEASE
Friday, April 13, 1984

HHS Secretary Margaret M. Heckler today ordered a suspension of the disability review process "until new disability legislation is enacted and can be effectively implemented."

She also ordered the Social Security Administration to continue benefit payments to all individuals who now have claims properly pending at all levels of administrative review as a result of the periodic review process.

Secretary Heckler's actions will allow benefits to continue for some recipients who, under current law, would receive their last disability checks May 3.

"I am taking this action so that no new periodic reviews are begun and no person with a claim properly pending before us loses benefits," Secretary Heckler said.

She announced she will work with Congress to enact disability legislation. The House has already passed a disability bill.

"I have talked with the leaders of the Senate Finance Committee and received assurance that they will act within the next few weeks," Secretary Heckler said. "I have pledged the full cooperation of our department in securing legislation that maintains our commitment to fair and humane treatment of the disabled."

"The Social Security Disability Program is a national program that requires consistent, nationwide criteria," she said. "Although we have made important progress in reforming the review process within Social Security, the confusion of differing court orders and state actions persists. The disability program cannot serve those who need its help when its policies are splintered and divided. For that reason, we must suspend the process and work together with Congress to regain order and consensus in the disability program.

"The time which we gain now can help us re-establish national criteria and also help the reforms which I announced last June take firmer hold in the disability review process," she said.

Heckler cited major improvements in the program since she announced reforms last June:

o The review process, formerly almost entirely a "paper" review of files, "has been replaced with a 'people process,' with increased face-to-face contact and more opportunity for beneficiaries to present their cases directly to Social Security and state agency employees," Heckler said.

o Nearly a million beneficiaries, or about one in four, have been exempted from the periodic review process by recognizing their impairments as permanent.

o Cases are now selected for review on a random basis so that no group is unfairly targeted, Heckler said.

o Difficult mental evaluation cases have been excluded from review pending re-examination of mental evaluation standards. New recommendations will be ready for publication soon, Secretary Heckler said.

o "A top-to-bottom review of disability policies is underway. Governnment and non-government physicians and vocational specialists are working together to improve disability criteria and to ensure fairness," she said.

"Despite these improvements, debate has continued on how the Social Security Administration should carry out the disability review process and which criteria are correct under the law," Secretary Heckler said. "I am determined to work with Congress to end this debate and clearly define criteria for determining continuing eligibility. Until a final decision is reached, the only fair thing to do is to stop the process, while at the same time protecting current beneficiaries."

The Continuing Disability Review was ordered by Congress in 1980 following findings that as many as one in five disability recipients might be collecting benefits improperly.

Under the new process which Congress established, disability cases were to be reviewed every three years to determine whether disability benefits were still warranted.

In announcing reforms in the program last June, Secretary Heckler blamed problems on "the old, paper-oriented review process we inherited." She called that process "too insensitive and too bureaucratic," and she aimed reforms at increasing face-to-face contact between reviewers and recipients, exempting more beneficiaries from the review, and improving criteria used to determine disability.

## LOW INCOME HOME ENERGY ASSISTANCE

Question: At the time the President's budget was submitted in January, it proposed maintaining the Low Income Home Energy Assistance Program at its then current level of $1,875,000,000. Subsequently, the President and the Congress passed a $200,000,000 supplemental, raising the fiscal 1984 level to $2,075,000,000. Have you considered amending your fiscal 1985 request to avoid a cutback below the revised fiscal 1984 program level?

Have all the supplemental funds now been allocated to the States?

Answer: Our request for a $200 million supplemental appropriation for this fiscal year was based on the abnormally cold weather of December and January. We believe that, under normal circumstances, $1.875 billion is sufficient to carry out the purposes of the program. We therefore do not intend to amend our request for reauthorization at $1.875 billion.

This request is consistent with the view that the program is meant to supplement other Federal and State programs, such as AFDC, SSI, and housing subsidies, which provide assistance with energy costs. Reauthorization at this level is based on consideration of the facts we have about the need for assistance, the other programs that also help meet this need, the flexibility given by the block grant to target assistance to households with the greatest need, and what States have done with LIHEAP funds in the past.

The President signed the supplemental appropriation bill in law on March 30. On April 2, we made grant awards for the entire amount of their supplemental allocations to the States, territories, and Indian tribes receiving direct LIHEAP grants, with the following exceptions:

- o Two States requested that some or all of their supplemental funds be awarded later. Per their request, we awarded 75 percent of Tennessee's supplemental allocation and will award the remaining 25 percent in the fourth quarter, and we will award North Carolina's entire supplemental allocation in the fourth quarter.
- o One State (Hawaii), one territory (American Samoa), and one tribe (Quapaw Tribe of Oklahoma) have submitted FY 1984 applications which are not yet complete. We therefore have not yet awarded any of their FY 1984 allocations.

## COMMUNITY SERVICES BLOCK GRANT

Question: Your statement rightly points out that no funds are requested for the Community Services Block Grant (CSBG) for which $343.6 million was provided in 1984. In your statement you say the Department proposes that States use other sources of funding, including the Social Services Block Grant. How much of an increase are you requesting for the Social Services Block Grant to compensate for this loss of funds for the Community Services Block Grant?

Answer: The Administration has requested the full authorization of $2.7 billion, an increase of $25 million for the Social Services Block Grant in 1985. However, there are other Federal funds which are used to provide services allowable under the CSBG Act, including Community Development Block Grants and Urban Development Action Grants administered by the Department of Housing and Urban Development (HUD), the Department of Agriculture's rural housing repair and community facilities development program, and various programs operated by the Department of Labor.

In addition, CSBG funds represent only 12 percent of total funding for Community Action Agencies (CAP) which by law must receive 90 percent of CSBG funds. In addition to the SSBG, CAPs receive funding from Head Start, the Low-Income Home Energy Assistance Program (LIHEAP) and the Alcohol, Drug Abuse and Mental Health Block Grant (ADAMHA).

## ENTITLEMENT ERROR RATES

Question: For fiscal 1984 Congress directed that the Department undertake a thorough study of the quality control system under which penalties are assessed the States for allegedly excessive error rates in Medicaid and Aid to Families with Dependent Children (AFDC). The Subcommittee was deeply disappointed, Madame Secretary, to receive your March 14 letter refusing to undertake the study. In the face of the claims by a number of States that the current quality control systems do not produce valid and reliable estimates of real errors ... do not produce timely information permitting effective corrective action ... and may unfairly penalize States that have performed well, why have you refused to re-examine this program?

Answer: First of all, let me assure you that I share your commitment to a fair and equitable quality control system designed to reduce Federal and State erroneous expenditures. The quality control system has evolved, over the last 10 to 15 years, through a cooperative process between the States and the Federal government. Furthermore, the quality control system has been the subject of numerous studies and has undergone continual review and refinement over the years. This process of review and refinement continues as State and Federal innovations are adopted. We believe that, through this process, we have successfully developed a methodology that does produce valid and reliable rates of errors and does not unfairly penalize any State that does not have an excessive error rate.

In addition, the quality control system does produce information on a timely basis, which enables the States to institute corrective action. States can and do use the quality control data on a continuous basis throughout the sample period to assist them in their efforts. They need not wait until the end of the sample period to analyze and track performance data. Moreover, this system has produced results; since the quality control system was established, erroneous payments, which American taxpayers finance, have significantly declined.

It is for these reasons that, after careful consideration within the Department, we determined that further study of the quality control system is not warranted.

Question: The States also are concerned that they are being denied adequate opportunity to comment on new quality control and fiscal sanctions that may in the end cost them money they can't afford. For example, we understand that new Medicaid rules were issued last June 24 as "interim final rules" and that new rules on the AFDC program have not yet been made available. To what extent are you trying to bar the States from this process?

Answer: We have attempted to provide States with every opportunity to comment on the rules implementing the TEFRA error rate provisions. With regard to Medicaid, since the statute requires that there be prospective withholdings, a regulation had to be implemented as quickly as possible. A revised regulation was published as an NPRM on August 31, 1983 and after considering the comments from the States and other outside parties was published as a final rule on December 1, 1983 for the periods beginning with January 1984. Moreover, the June 24 interim final rule was published in final form on February 8, for the period of April - December 1983, after careful consideration of all comments received. In the case of AFDC, we expect an NPRM to be published shortly.

Further, our good faith effort to provide the States adequate opportunity to comment on the Medicaid rules of June 24 was demonstrated in a recent court decision (State of New Mexico, et al., v. Heckler; U.S. District Court for the District of Columbia civil action 83-1982). In that decision, it was found that our publications of the revised regulations and the final rule to the June 24 regulation rendered moot the States arguments against this June 24 interim final rule. Therefore, the case was dismissed.

Question: It's been suggested to us that the quality control process could be improved by not counting technical errors in determining error rates and by including some exemption for errors caused by welfare clients and differences in socio-economic conditions among the States. Why not make these improvements?

Answer: In Medicaid, technical errors are explicitly excluded by statute from the error rates. AFDC quality control monitors basic conditions of eligibility and payment. The so-called "technical errors" are, in fact, statutory requirements that must be met to qualify the payment for Federal matching funds. For example, the requirement that applicants provide or apply for a Social Security number is essential to the proper and efficient administration of the AFDC program. Without the Social Security number, welfare agencies are effectively prevented from conducting computer matches with banks, Social Security Administration's wage data or Title II benefit data files, State Employment Security offices, etc., in order to verify the initial and continuing eligibility of the recipient.

With respect to differentiating between client and agency-caused errors or socio-economic conditions, no provision exists in the statute to make these distinctions. However, TEFRA does provide for matching erroneous payments up to a 3 percent tolerance level. This may be viewed as an accommodation to errors States believe they cannot control. We believe that client-caused errors are controllable by computer matches and the development of procedures for ensuring prompt reporting from clients. The inclusion of client-caused errors provides a strong incentive for States to develop these systems and procedures.

## CHILD CARE

Question: I'm concerned that your fiscal 1985 budget will further deteriorate already inadequate help to low-income people who need child care services in order to work. You are proposing, for instance, that the Social Services Block Grant -- which is the major Federal program providing child care assistance -- absorb the Community Services Block Grant, but with an overall cut of $320 million. You are also once again proposing the idea rejected last year of having Head Start directly finance child care feeding activities now provided by the Agriculture Department -- raising concerns that future appropriations might not adequately meet nutritional needs covered by the Child Care Feeding program. You further propose elimination of the $166 million Work Incentive Program, which provides child care for welfare recipients enrolled in job training projects. Won't these proposals make it even more difficult for low-income families to become self-sufficient or keep their jobs?

Answer: To the contrary, we believe that these proposals will serve to make more effective use of Federal funds through existing programs which serve low-income families. We have found that the Community Services Block Grant (CSBG)-funded activities in large measure overlap activities that are being funded through other programs, mainly the Social Services Block Grant (SSBG). In addition, we chose not to request funding for the Work Incentive Program because, as GAO has demonstrated, this program is not cost-effective. As an alternative, we propose a legislative change in the AFDC program that would require all employable adults to participate in job search and community work experience programs, in addition to simply registering for work. The budget includes $158 million to reimburse States for the administrative costs associated with implementing this proposal. As you know, in proposing to have Head Start directly finance the Child Care Feeding Program, we have requested $80 million in 1985 for this purpose, an increase of $4 million over estimated child care nutrition funding in 1984.

There exists substantial Federal support to assist families and communities in addressing their needs for child care services. The Federal tax credit for child and dependent care alone provided families nearly $2 billion in credits for child care expenses for calendar year 1982. In addition, States may of course use funds received under the $2.7 billion SSBG program for the provision of child care services to low income families.

## SERVICES FOR CHILDREN

Question: I would like to call your attention to a booklet recently published by the Connecticut Association for Human Services and the Junior League of Hartford, entitled "Growing Up at Risk in Connecticut."

Just a few excerpts from this publication will clearly illustrate the deterioration of services in recent years to children desperately in need of help.

"One in seven children under 6 lives below the poverty level" (p. 12). "Between 1970 and 1980 the poverty rate for children under 6 in Connecticut increased by 58%" (p. 15).

"In 1973, Connecticut's AFDC grant was set at 91% of the poverty level. Currently, it is set at only 66% of the poverty level for a family of three."

"Between 1980 and 1983, in Federal funding alone, there has been a 22.3% decrease for children's programs in Connecticut" (p. 10).

"The vast majority of publicly funded day care centers which are open to low-income families have waiting lists" (p. 49).

"Only one-quarter of eligible children are enrolled in Head Start programs" (p. 78).

"Soup kitchens and emergency food banks in Connecticut report an increase in demand for assistance of up to 400% since 1980 ... (with) a notable increase in the number of families with children requesting help" (p. 45).

In view of this sorry picture, do you really feel your fiscal 1985 budget is all we can afford on behalf of our needy children?

Answer: President Reagan is committed to helping children in need. The Administration's budget and program reforms also reflect a real concern for children and provide an effective response to their needs. My budget includes $21 billion to assist children directly, through such programs as the Maternal and Child Health Block Grant, AFDC, Head Start, and Child Support Enforcement, an increase of $3 billion since FY 1980. In addition, other major HHS programs indirectly benefit children through help for their families.

Other HHS initiatives have also strengthened the effectiveness of children's programs. Prior to the Reagan Administration, many health and human services programs were poorly targeted, fraught with fraud and waste, and improperly dependent on Federal funding and administration. For service programs and Medicaid, this Administration gave States and localities more discretion to decide how best to use resources to alleviate problems. States have responded to this flexibility responsibly, as the recent GAO studies on the HHS block grants have shown. For welfare, we have aimed at achieving real, permanent solutions by encouraging work, preventing welfare dependency, and targeting program benefits on the most needy. An important priority for the Administration is passage of legislation to improve the Child Support Enforcement Program. This legislation will place greater responsibility on absent parents for the care of their children in order to prevent the need for welfare.

In other programmatic areas, we are maintaining strong progress. Major examples include the following: childhood immunization levels are at historic highs of 95 percent and immunization funding has increased almost 40 percent since 1980. We are maintaining a strong commitment to research out the causes and cures of childhood disease. The FY 1985 request for the National Institute of Child Health and Human Diseases is $160 million, an increase of $8 million over FY 1984 and $38 million over FY 1980. The request for Head Start, exclusive of the U.S. Department of Agriculture Child Care Feeding Program, is $996 million which is $261 million or 35 percent more than the FY 1980 appropriation.

Clearly, one of the best ways to help our needy children is to have a strong American economy--an economy which allows families to achieve and sustain economic self sufficiency. The Reagan Administration's economic recovery program has resulted in an increase in employment of almost 5 million persons since the 1982 recession and employment is now at an all-time high of 104 million persons. This is the largest gain in any post-World War II, 15-month period. Thus we expect that 1983 and 1984 poverty data, when available, will show that the poverty rate among children has declined substantially, in particular for children in two-parent families. This recovery has also lowered interest rates and inflation thereby benefitting families with limited resources.

With respect to the particular figures for Connecticut quoted from the Junior League booklet, it should be noted that the AFDC grant level and the allocation of Federal grant funds for particular services within Connecticut are established by the State. Therefore, some of the funding and benefit limitations alleged in "Growing Up at Risk in Connecticut" are, if accurately estimated, a result of decisions made by that State.

## IN VITRO FERTILIZATION RESEARCH

Question: I understand NIH is losing one of its top scientists in the field of test tube fertilization because each experiment must be approved by an Ethics Advisory Board and the Board was allowed to expire in 1980. It's within your power to reconsititute the Ethics Advisory Board by regulation, as I understand it. Why haven't you done so?

Answer: Yes, it is within my authority to charter an Ethics Advisory Board. How best to provide review concerning the ethical aspects of human in vitro fertilization and embryo transfer research is a sensitive and complex issue and, from my perspective, one which requires a most deliberate and thorough decision-making process. Thus the Department is proceeding with all due caution in considering this important matter.

Question: Is it true that you were given a proposal to reestablish the Board last summer, but you still haven't acted on it?

Answer: The Public Health Service has identified various approaches for considering research proposals which require review by an ethics panel. This matter remains under Departmental review.

Question: It's our understanding that this hiatus in reestablishing the Ethics Advisory Board has stymied research in a field that really needs more research. What are your comments?

Answer: I recognize that further research in this field may be beneficial and wish to point out that related research, in fact, is ongoing.

Question: What work can NIH do in this area in the absence of an Ethics Advisory Board?

Answer: In the absence of an Ethics Advisory Board, NIH may support in vitro fertilization research on animals.

Question: How many births from test tube fertilization have occurred in the U.S. and how many world-wide?

Answer: There have been approximately 75 births from in vitro fertilization in the U.S. and some 500 or more in other countries.

## EXPIRING PROGRAMS

Question: You are not proposing to renew expiring authorizations for several programs, such as health planning, home health, and tuberculosis grants. In the event renewed authorizing legislation is delayed, do we have your assurances that you will not prematurely begin to phase out these activities given the likelihood that a Continuing Resolution would maintain their funding level in fiscal 1985?

Answer: We have no plans to begin phasing out these programs until it is clear that Congress does not intend to reauthorize and refund them.

## DISABILITY REFORMS

Question: It is my understanding that this Department has made a number of administrative reforms to make the disability decision-making process more equitable. Exactly what has the Department done?

Answer: The periodic review of disability beneficiaries mandated by the Congress in 1980 brought to light the need for a number of fundamental changes in the disability decision-making process. Beginning early in 1982, the Department began implementing a series of administrative reforms in the disability program. Additional reforms were implemented in June 1983 to make the program more responsive to the needs of beneficiaries while assuring that we fulfill our obligations to Congress and the taxpaying public to administer the program in an efficient and effective manner.

The most important of the reforms included:

- Reducing the number of beneficiaries to be reviewed every three years by expanding our definition of permanent disability;
- Suspending the review of mentally impaired beneficiaries with functional psychotic disorders until we revise the review criteria;

- Beginning each continuing disability review with an interview in a local Social Security office;
- Initiating a top-to-bottom review of disability policies and procedures in consultation with appropriate outside experts and the States.

Our top-to-bottom review of the program is well underway. As part of this review, a group made up of outside experts as well as SSA State agency personnel has been revising the criteria for evaluating mental impairments. We hope to publish the findings of the mental impairment workgroup for public comment in late April. Also, we are now implementing face-to-face evidentiary hearings at the reconsideration level of the appeals process which should help to asure that any erroneous disability decisions will be corrected in the appeals process.

Most recently, on April 13, I announced (1) a suspension of the disability review process until new disability legislation is enacted and can be effectively implemented, and (2) a continuation of benefits to all individuals who have claims properly pending at all levels of administrative review as a result of the periodic review process.

These actions were taken in recognition of the continuing debate on how the Social Security Administration should carry out the disability review process. As I said on April 13, I believe that, in the interim period, the only fair thing to do is to stop the process, while at the same time protecting current beneficiaries.

Question. Have the new procedures reduced the number of erroneous terminations?

Answer: Yes. We believe the improvements implemented to date (for example, providing a face-to-face meeting with the disability beneficiary at the very beginning of the CDR process and suspending the reviews of mental impairment cases until revised standards are issued) have corrected the most serious problems in the review process and reduced the number of erroneous terminations.

Question: In an effort to protect their residents, and to adhere to rulings of Federal courts, a number of States have imposed moratoriums on the disability review process until Congress passes a reform bill or the Department makes administrative improvements. What position has the Administration taken with regard to State moratoriums?

Answer: On April 13, 1984, I ordered a suspension of continuing disability reviews until new disability legislation can be enacted and effectively implemented. This moratorium addresses the problems created by individual State moratoria and the use of varying standards in the disability determination process. As I said in announcing the moratorium, the Social Security Disability Program is a national program that requires consistent, nationwide criteria. Although we have made important progress in reforming the review process within Social Security, the confusion of differing court orders and State actions persists. The disability program cannot serve those who need its help when its policies are splintered and divided. For that reason, we must suspend the process and work together with Congress to regain order and consensus in the disability program.

## WIN DEMONSTRATION

Question: The authorization for operating Work Incentive demonstration programs expires at the end of fiscal 1984. If Congress continues to fund the Work Incentive Program at its current level in fiscal 1985, what will happen in States which have expiring demonstration projects in the absence of renewed authorizing legislation?

Answer: We expect that the WIN Demonstration Program States having completed the three-year program will then meet the legislative requirements of SSA Part IV C, and return to regular WIN operations. Some of the innovations in administration and service delivery which have developed in the demonstration program can be continued after the three-year period through waivers, increased flexibility, etc. Efforts will be made to incorporate other innovations found to be effective into new legislation and regulations.

## REPORT LANGUAGE DIRECTIVES

Question: Specifically, how much do you intend to spend in each of fiscal years 1984 and 1985 for Aging research activities with National Legal Services organizations?

Answer: Funding levels for all legal services activities in FY 1984 will be continued at the FY 1983 level. Specific funding levels for Aging research projects for National Legal Services organizations, however, will depend on the outcome of a competitive grant review process as announced on October 18, 1983 in the Federal Register; as a result, we do not at this time know what final level of funding will be provided to these organizations in FY 1984. Funding in FY 1985 will also depend on the outcome of the competitive grant review process.

Question: How much will you spend for Head Start evaluation, research and demonstration activities?

Answer: In 1984, Head Start will spend $1.8 million for traditional Head Start research, demonstration and evaluation activities and will fund at least $3 million of innovative local demonstration projects from applications submitted in response to the announcement for use of additional Head Start expansion funds provided by the Congress. This compares with the FY 1985 budget request of $1.3 million and FY 1983 obligations of $7.1 million.

UNAUTHORIZED PROGRAMS

You are requesting $5.8 billion for programs which have not yet been reauthorized by Congress for FY 1985. This represents half of your entire budget for discretionary programs.

Question: Are there any programs for which you have not yet transmitted specific legislation to the authorizing committees?

Answer: There are 75 appropriations authorizations which expire in FY 1985. Of these, we are requesting reauthorization of 43, repeal of 11 and consolidation of 21. Some of the reauthorization legislation was transmitted to the Congress in FY 1983, a number of draft reauthorization bills have already been sent to the Congress this year and the remainder will be transmitted shortly. In the case of PHS authorities and some HDS authorities for which reauthorization requests were submitted last year, we will resubmit them again, as we are preparing new bills which, for clarity of presentation, combine our proposals of last year with several new ones. I have attached a list of the expiring appropriations authorities and the status of our draft legislation. The information follows.

Expiring Authorities—Status of HHS Legislation

| Bill/Program | HHS Recommendation | Draft Bill To Congress |
|---|---|---|
| Health Research | | Forthcoming |
| Health Services Research | Reauthorize | |
| Health Statistics Activities | Reauthorize | |
| Medical Library Assistance Program | Reauthorize | * |
| National Cancer Authority (Prevention and Control and Cancer Activities) | Reauthorize | * |
| National Heart, Lung, and Blood Institute (Prevention and Control and Heart Activities) | Reauthorize | * |
| Diabetes Data System | Reauthorize | * |
| Diabetes Research and Training Centers | Reauthorize | * |
| National Diabetes Advisory Board | Reauthorize | * |
| National Arthritis Advisory Board | Reauthorize | * |
| National Digestive Diseases Advisory Board | Reauthorize | * |
| Arthritis Data System | Reauthorize | * |
| Multipurpose Arthritis Centers | Reauthorize | * |
| National Research Service Awards | Reauthorize | * |

* Also included in the PHS Act Amendments of 1983, transmitted to the Congress on 3/4/83.

| Bill/Program | HHS Recommendation | Draft Bill To Congress |
|---|---|---|
| Alcohol Research Programs | Reauthorize | * |
| Drug Abuse Research Programs | Reauthorize | * |
| Health Promotion | Reauthorize | * |
| National Panel for Alcohol, Drug Abuse, and Mental Health | Repeal | * |
| Physical Fitness and Sports Medicine | Repeal | * |
| Health Services |  | Forthcoming |
| Project Grants for Immunization Services | Reauthorize |  |
| Venereal Disease Grants | Reauthorize |  |
| National Health Servce Corps Field Program | Reauthorize |  |
| Preventive Health and Health Services Block Grant | Reauthorize |  |
| Alcohol, Drug Abuse, and Mental Health Service Block Grant | Reauthorize |  |
| Primary Care Block Grant | Consolidate |  |
| Migrant Health |  |  |
| Family Planning |  |  |
| Black Lung Clinic |  |  |
| Adolescent Family Life Program | Reauthorize |  |
| Office of Population Affairs | Repeal | * |
| Health Professions Training |  | Forthcoming |
| Health Education Assistance Loan Program | Reauthorize |  |
| Assistance to Health Professions Students from Disadvantaged Backgrounds | Reauthorize |  |
| Advanced Financial Distress Assistance | Reauthorize |  |
| Primary Care Physicians Training | Consolidate |  |
| Area Health Education Centers |  |  |
| Health Professions Special Projects |  |  |
| Health Administration and Health Traineeship Program |  | * |

* Also included in the PHS Act Amendments of 1983, transmitted to the Congress on 3/4/83.

| Bill/Program | HHS Recommendation | Draft Bill To Congress |
|---|---|---|
| Preventive Medicine Residency Program } | | |
| Nursing Special Projects } | | |
| Advanced Nurse Training } | | |
| Nurse Practitioner } | | |
| Health Maintenance Organizations | | Forthcoming |
| Grants and Contracts for Feasibility Studies | Repeal | * |
| Grants, Contracts, and Loan Guarantees for Planning and for Initial Development Costs | Repeal | * |
| Loan and Loan Guarantees for Ambulatory Health Care Facilities | Repeal | * |
| Training and Technical Assistance to HMO's | Repeal | * |

* Also included in the PHS Act Amendments of 1983, transmitted to the Congress on 3/4/83.

| Bill/Program | HHS Recommendation | Draft Bill To Congress |
|---|---|---|
| Indian Health | | Forthcoming |
| Indian Health Professions | Reauthorize | |
| Health Services to Indians | Reauthorize | |
| Indian Health Care Facilities | Reauthorize | |
| Indian Safe Water and Sanitary Waste Disposal Facilities | Reauthorize | |
| Health Services for Urban Indians | Repeal | |
| Health Planning | Repeal | 3/4/83 |
| Child Abuse and Adoption Opportunities | | 3/8/83 |
| Child Abuse Prevention and Treatment Program | Reauthorize | |
| Adoption Opportunities | Reauthorize | |
| Child Welfare | | Forthcoming |
| Child Welfare Services } | Consolidate | ** |
| Child Welfare Training } | Consolidate | ** |

* Also included in the PHS Act Amendments of 1983, transmitted to the Congress on 3/4/83.

** Also included in the Child Welfare and Foster Care Amendments, transmitted to the Congress on 3/4/83.

| Bill/Program | HHS Recommendation | Draft Bill To Congress |
|---|---|---|
| Community Services Block Grant | Repeal | 4/27/83 |
| Older Americans Act | | 3/27/84 |
| Nutrition and Services | Consolidate | |
| --Support Services | | |
| --Congregate Meals | | |
| --Home Delivered Meals | | |
| --Commodities/Cash Meals Assistance (USDA Authorities) | | |
| --State Plan Administration | | |
| Federal Council on the Aging | Reauthorize | |
| Direct Grants to Indian Tribes | Reauthorize | |
| Training, Research, and Discretionary Projects and Programs | Reauthorize | |
| Head Start | Reauthorize | 3/20/84 |
| Runaway and Homeless Youth | Reauthorize | 3/7/84 |
| Native Americans Program | Reauthorize | 3/27/84 |
| Developmental Diabilities | | Forthcoming |
| Basic State Grants | Reauthorize | |
| Protection and Advocacy | Reauthorize | |
| University Affiliated Facilities | Reauthorize | |
| Special Projects | Reauthorize | |
| Work Incentives Program | Repeal | 5/25/83 |
| Low-Income Home Energy Assistance Program | Reauthorize | 2/29/84 |
| Refugee Assistance | Reauthorize | 6/7/83 |

Question: Would you endorse maintaining these programs at their current levels under a Continuing Resolution, in the absence of renewed authorizing legislation?

Answer: I would rather see the programs reauthorized at the levels we proposed, although I would, of course, endorse the continuance of the authorities under a Continuing Resolution, rather than seeing them expire, to the extent that we've requested funding in the President's budget. Usually a Continuing Resolution is for a one-year period or less and does not eliminate, but merely postpones, the task of enacting reauthorization legislation. Furthermore, it usually does not include legislation changes to improve the programs so they can function more effectively and efficiently.

### ELIMINATING AUTHORIZED PROGRAMS

You are once again proposing to abolish certain programs that are authorized for FY 1985, such as the Community Services Block Grant and the Work Incentive Program.

Question: Why don't you propose that the authorizing committees repeal these statutes, rather than eliminating programs through the "back door" of zeroing out their funding?

Answer: We have or will be proposing statutory changes to repeal programs for which we recommend no funding.

For example, on April 27, 1983, I sent to the Congress a draft bill to repeal the Community Services Block Grant (CSBG). On the same date, I sent a companion bill to amend the Social Services Block Grant to clarify that its funds may be used for many of the activities and programs currently funded under the Community Services Block Grant.

On May 25, 1983, I sent to the Congress a draft bill entitled "Social Welfare Amendments of 1983." It includes a provision to repeal the WIN program. In its place, the Community Work Experience program would be strengthened and made mandatory, and employment search would be required of AFDC applicants and recipients.

Similarly, I have or will be sending to the Congress bills to repeal the statutory authority for all other programs which we consider should be funded now or in the future.

It should also be noted that both CSBG and WIN are discretionary programs and that it is well within the power of the appropriations committees to fund them at zero or any other amount less than their authorized level. There are many unfunded discretionary authorizations within HHS legislation.

### SOCIAL SERVICES BLOCK GRANT

Question: Following enactment of $2,675,000 for the Social Services Block Grant in fiscal 1984, authorizing legislation was also enacted to raise this appropriated entitlement to $2,700,000,000. Why is it that you have not requested a $25,000,000 supplemental?

Answer: The Social Services Block Grant is an appropriated entitlement and is therefore dependent upon appropriation action to set its funding level, currently not to exceed the $2.7 billion. The authorization level was raised by the Congress after the initial 1984 appropriation and after the Department submitted the 1985 request to the Office of Management and Budget, and the Administration assumed the Congress would take the appropriations actions necessary as a result of the change in the reauthorization level.

Question: Can you supply the Committee with a legal opinion that you are not required to spend any more than the appropriated amount for this entitlement program?

Answer: The opinion follows.

**April 3, 1984**

Donald Hirsch dh
Assistant General Counsel

Unavailability of deficiency apportionment to fund social services block grant authorization

Mr. Anthony Itteilag
Deputy Assistant Secretary, Budget

Title XX of the Social Security Act, enacted in its current form by the Social Services Block Grant Act (§ 2351 of P.L. 97-35), provides, in pertinent part:

> Sec. 2002. Each State shall be entitled to payment under this title for each fiscal year in an amount equal to its allotment for such fiscal year . . .

Each State's allotment for fiscal year 1984, under section 2003 (as amended on October 4, 1983 by § 204 of P.L. 98-135), is a proportionate share of $2.7 billion (reduced by a small amount in consequence of payments to territories). The appropriation for title XX for FY 1984, as contained in the Department of Health and Human Services Appropriation Act, 1984 (title II of P.L. 98-139, enacted on October 31, 1983) is not, however, $2.7 billion, but $2.675 billion: $25 million less than the allotment base. Your question to me is whether OMB is authorized to apportion the quarterly title XX grants to the States using the higher number.

In our opinion it is not so authorized.

Because Congress has not appropriated the $25 million difference between the allotment base and the amount included in P.L. 98-139, an apportionment based on $2.7 billion would create a deficiency in the fourth quarter. Under 31 U.S.C. 1515, a deficiency apportionment is authorized only because of--

> "(A) a law enacted after submission to Congress of the estimates for an appropriation that requires an expenditure beyond administrative control: or
>
> "(B) an emergency involving the safety of human life, the protection of property, or the immediate welfare of individuals when an appropriation that would allow the United States Government to pay, or contribute to, amounts required to be paid to individuals in specific amounts fixed by law or under formulas prescribed by law, is insufficient."

The $2.675 billion appropriation was enacted after the enactment of the allotment base increase. There is therefore no argument that paragraph (A) might apply.

Of the remaining conditions, the only one that might arguably apply is the condition authorizing a deficiency apportionment in order to provide for the immediate welfare of individuals. However this condition specifies that the context must be a statute allowing the United States Government to contribute to "amounts required to be paid to individuals in specific amounts fixed by law or under formulas prescribed by law". Title XX, to the contrary, specifically forbids cash payments to individuals except in extraordinary circumstances. And even in extraordinary circumstances no amounts are prescribed, specifically or by formula. See sections 2005(a)(2), 2005(a)(3), 2005(a)(8), and 2005(b).

For these reasons a deficiency apportionment is not available.

Question: In your opinion, could an additional $25,000,000 be effectively used in FY 1984 for Social Services Block Grant activities?

Answer: Because States have already made their plans for 1984 and because this money would become available so late in the year, the States will be able to carry out effective programs this fiscal year without the $25,000,000.

## HEAD START

Question: Your budget justification states "In 1985, Head Start programs will no longer receive Department of Agriculture reimbursements. Instead, they will receive these funds directly as part of their Head Start grants" (page 45). Does this mean you plan to proceed administratively to implement a change that was rejected by Congress last year?

Answer: No, we are not going to proceed administratively. We specifically are asking the Congress to approve appropriations for this purpose in the FY 1985 budget.

Question: How do you expect to maintain last year's level of Head Start enrollees when you are not requesting increased funding to offset inflation?

Answer: Head Start grantees increased the permanent enrollment nationwide by 9,000 children from FY 1982 to FY 1983 without an increase in the appropriation. They did this by more efficiently using their available funds (e.g., reducing carryover balances so that more dollars were available to enroll children). We expect that Head Start grantees will continue to improve in this aspect and will be able to maintain the FY 1984 enrollment level in FY 1985.

Question: How long has it been since the Head Start appropriation contained funds specifically intended for teacher salary raises?

Answer: The last Head Start appropriation containing funds specifically intended for teacher salary raises was for FY 1982.

## WORK INCENTIVE PROGRAM

Question: Last year's hearing record indicates that in fiscal 1982, the Work Incentive Program produced welfare savings nearly double its cost. Although this year's budget no longer includes an estimate of welfare saving, it shows job placements going up 33 percent in fiscal 1984 over 1982, despite no increase in Federal funding. Do these statistics mean that you expect even bigger welfare savings in fiscal 1984?

Answer: In FY 1982, the WIN program experienced funding reductions coupled with instructions from the Department of Labor to phaseout the program by September 30, 1982. This resulted in a significant reduction in staff and the level of unsubsidized employment. Thus, the FY 1982 actual employment numbers are not comparable to the FY 1984 planned employment numbers because 1982 was not a year of comparable program activity. However, FY 1983 and FY 1984 comparisons are valid because of stable funding and administrative direction. The FY 1984 increase in employment is planned to be 5 percent above the 1983 level. In addition, we expect a proportionate increase in the planned 1984 welfare grant reductions over the 1983 figures.

Question: Since the WIN program consistently appears to have more than paid for itself, why are you proposing to abolish it?

Answer: We do not believe that the WIN program is cost-effective. The General Accounting Office (GAO) estimates that for every $4 spent on the WIN program, only $1 in AFDC grant reductions can be attributed directly to WIN placements. When Medicaid and Food Stamp savings are considered, total savings still amount to only $2 for every $4 of WIN expenditures. GAO also reported that only 36 percent of WIN registrants actually entered employment and most of them (70 percent) said they found their own jobs with little or no help from the WIN program. In view of these findings, we believe that mandatory job search and community work experience programs are more cost-effective alternatives to the WIN program.

### GAO REPORT ON ELDERLY JOBS PROGRAM

Question: The President's budget proposes to transfer a portion of the Labor Department's elderly jobs program to the Administration on Aging in HHS. What advantage would there be in having two Federal agencies share funding under the Community Services Employment for Older Americans program?

Answer: The two portions of the Title V program -- national contractors and the State funding -- are run independently of each other at the project level. However, most of the 22 percent of the program that is funded through the States is administered by State agencies on aging. Since the primary source of support of the aging network is the Administration on Aging, we believe that it would be administratively efficient to have the State portion of the program channeled through AoA.

Question: How do you respond to the General Accounting Office's recent report that it "did not find any studies, evaluation, or other documentary evidence to indicate that program effectiveness and coordination would increase," if the proposed transfer took place?

Answer: We defer to the Department of Labor for a detailed response to the GAO report. We would note, however, that the GAO report addressed an earlier Administration proposal to transfer the entire Title V program from the Department of Labor to DHHS. This transfer is no longer proposed; instead, in 1985 the Department proposes only to include the State portions of Title V monies as part of a single grant to States for Aging Supportive and Nutrition Services, in order to reduce the coordination between Labor and HHS which States now face. In addition, the GAO report itself notes, in an introductory statement, that the GAO was "unable to make a comprehensive assessment on how well the program is currently run and whether it should be moved" because they "limited the scope and duration of our survey to meet the subcommittee's needs within their timeframe."

## CHILD CARE

Question: We understand the Administration has been encouraging employers to augment day care facilities, and proposes greater child care tax credits. But can these initiatives really help people who earn only $10,000 and have to pay 25 percent or more of their salary for child care services?

Answer: Yes. These efforts will provide substantial assistance to low income families needing child care.

Under the Administration's child care tax credit proposal, a family earning $10,000 and spending $2,500 on child care would receive a tax credit of $1,000. This is $250 more than under current law. While it is quite unusual for a family to spend such a high proportion of its income on child care, we believe that $1,000 in Federal support is a substantial amount of assistance to such a family.

The tax credit is not the only source of child care assistance for low income families. There are also programs and initiatives of private employers and local governments, as well as several Federal programs (including the Social Services Block Grant and the AFDC work expense disregard). This combination of initiatives provides parents with the most flexibility and options in meeting their child care needs. Many private programs are expanding. For example, between 1978 and 1982, private sector initiatives in child care increased by 296 percent, and those initiatives are expected to continue to increase. These combined efforts really do help parents with their child care needs.

## WASTED DOLLARS

Question: Dr. Arnold Relman, Editor of the New England Journal of Medicine, recently expressed concern that $5 to $10 billion a year is being wasted on useless or dangerous medical technologies and almost as much on marginal ones not worth what they cost? How is the Department responding to this concern?

Answer: In general, the Department shares Dr. Relman's concerns. However, we do not have the data to know which technologies, under what circumstances, and for which patients a technology may be so classified, nor what the dollar cost of such waste amounts to. We do not believe that the government should make decisions about who should receive a particular technology, who should provide that technology, or where the technology should be provided. The Public Health Service, specifically the National Center for Health Services Research (NCHSR), provides clinical and scientific information about technologies and makes recommendations to HCFA on Medicare reimbursement for certain technologies. Also, NCHSR's extramural research program supports the development of methodologies for technology assessment, analyses of cost benefits and cost effectiveness, and development of evidentiary standards. Through the Technology Coordinating Committee, comprised of government and industry representatives and chaired by NCHSR, we have in place a forum to discuss and take action on matters relating to technology assessment.

### NCHCT ROLE

Question: Are you familiar with the National Center for Health Care Technology (NCHCT) established by Congress in 1978?

Answer: Yes, the National Center for Health Care Technology began operation in FY 1979 and continued as a separate organizational entity through FY 1981. In FY 1982 Congress concurred with the President's request to terminate NCHCT and transfer its functions to the National Center for Health Services Research.

Question: What has been the role of the National Center for Health Care Technology that was established by Congress in 1978?

Answer: The National Center for Health Care Technology had responsibility for developing and expanding the knowledge base in methods of assessing medical technologies and conducting comprehensive assessments. The Center concentrated on technologies that involved individual patients. An integral part of its responsibility was to provide recommendations to the Health Care Financing Admininstration on Medicare coverage for specific technologies.

When the activities of NCHCT were terminated, the National Center for Health Services Research assumed the major responsibility of technology assessment research and the Medicare coverage activity.

### TECHNOLOGY ASSESSMENT

Question: The Washington Post in a recent report said that Dr. Seymour Perry who headed the Center claims that no agency is truly assessing new medical technologies. Is that true?

Answer: We believe that, in general, it is not the role of the Federal government to do all technology assessment that needs to be done. An Institute of Medicine study looked at the whole issue of technology assessment and its report recommended that a private entity be established encompassing the medical and engineering fields to which all relevant bodies would contribute and provide policy direction to begin the process of evaluating technologies.

As a matter of specific practice, the National Center for Health Services Research (NCHSR) assesses new medical technologies at the request of the Health Care Financing Administration (HCFA) to give medical advice regarding the appropriateness for coverage under Medicare. When inquiries regarding coverage are received by HCFA, a physicians panel that includes a representative from NCHSR, reviews the issue. If the panel determines that an assessment is required, the question is referred to NCHSR. The NCHSR staff consult with appropriate experts from NIH and FDA, review the available literature, solicit views from relevant medical specialty and subspecialty groups, and provide an opportunity for the developers of the technology to supply additional material they wish to have considered. A preliminary assessment document is prepared and sent to NIH and FDA for comment. The final document is forwarded to HCFA along with a recommendation that may be for coverage, against coverage, or for coverage for special conditions. HCFA then makes the actual coverage decision.

## ADEQUACY OF ASSESSMENTS

Question: Are you doing an adequate job of assessing new medical technologies and more importantly, are you disseminating your findings?

Answer: The Public Health Service is adequately assessing technologies for Medicare coverage at the request of the Health Care Financing Administration. In addition to making recommendations to HCFA on coverage issues, NCHSR disseminates these findings to insurance companies and other interested groups. Some of the means used to reach the broad audience interested in these findings include:

- publication in professional journals;
- an Annual Technology Guide published by the American Hospital Association;
- monthly NCHSR Research Activity Reports;
- archiving through the National Technical Information Service.

## CONSULTANT AND RELATED SERVICES

Question: One area that has been of continuing concern to the Subcommittee is the amount requested for consultant and related services. It would be helpful to the Subcommittee to have a table listing the amounts requested for consulting services with the appropriations accounts from which the amounts are to be paid as well as a description of the need for the consulting services. How do these amounts compare to FY 1984 amounts for consulting services?

Answer: Our request for consultant and related services for FY 1985 is $108.6 million. This represents no growth from our projected FY 1984 obligations, actually a $1.6 million decrease.

Our consultant services request for FY 1985 is $57.0 million. Consultant services are advisory in nature and relate to the governmental functions of agency administration and management. This advice is provided by persons and organizations who have knowledge and special abilities that are not available within an agency.

Our related services request for FY 1985 is $51.5 million. Related services provide several types of assistance also not available within a governmental agency. These services fall into three categories: management and professional services; special studies and analyses; and management and professional services for

Research and Development (R&D) activities that are funded with R&D money.

A table is provided that shows the FY 1984 estimated obligations and FY 1985 budget request by account. A detailed description of the needs and uses of consultant and related services has been provided in each volume of the Congressional Justification of Appropriation Estimates for Committee on Appropriations Fiscal Year 1985. The following are highlights of the activities to be conducted with these funds in FY 1985.

Consultant Services

- National Institutes of Health - NIH utilizes consultant services funds to secure the services of the members of its legislatively mandated advisory committees and the "study sections" which constitute the heart of its grant and contract peer review system. In addition, consultant services are used to assist in developing and monitoring research initiatives and for prevention efforts such as AIDS, Alzheimer's Disease, diabetes, and immunology.

- Alcohol, Drug Abuse and Mental Health Administration - ADAMHA utilizes consultant services to secure the services of the members of the National Advisory Council and initial review groups. These are integral parts of the peer review process, ensuring the quality of research. The peer review process ensures that a knowledgeable and objective review is applied to all grant applications. In addition, ad hoc review groups are used to review applications requiring expertise not available; where potential for a conflict of interest is probable; or where there is no chartered review committee. This process is the foundation for ensuring excellence in the grant programs and enhances the achievement of the public objective for which grant funds are appropriated. Evaluation projects will be used to assess ongoing prevention programs and statistical reporting programs.

- St. Elizabeths - Expanded A-76 reviews will be supported to determine the feasibility of contracting out the provision of certain services.

- Health Care Financing Administration - Copayment restructuring efforts and the impact of uniform billing upon programs and information systems will be evaluated.

- Social Security Administration - SSA will continue to develop a cost effectiveness standard for the States' Offices of Disability Determination Services function; will start several projects related to SSA's methods of determining mental disability; and will evaluate and analyze the effect of economic trends (such as employment and inflation) on child support enforcement collections and expenditures for each State to help in the planning of child support enforcement objectives.

Related Services

- National Institutes of Health - Assessment of current policies for the use of laboratory animals in biomedical research will be conducted. Statistical studies of Federal and international support of health research will be supported as will software and programming at the NIH computer facility.

- Alcohol, Drug Abuse and Mental Health Administration - Public education campaign materials will be produced for dissemination by the States. Selected research activities will be supported, such as the production of chemical substances for research use and drug abuse liability testing. The National Clearinghouse for Alcohol Information, the Secretary's Initiative on Teenage Alcohol Abuse, and outreach efforts to assist in nationwide prevention and treatment efforts will be funded.

- Office of the Assistant Secretary for Health - Related services funds will be used primarily in the gathering of data and development of the National Center for Health Statistics (NCHS) "vital" statistics reports. Remaining funds will support smoking and health and health promotion media campaigns and other NCHS statistical reporting activities.

- Health Care Financing Administration - Related services will support:

  - -- development of a quality of care monitoring system;

  - -- the implementation of a National Standards and Certification Monitoring System;

  - -- implementation of an improved program monitoring system to review hospital admissions, discharge patterns, and quality of care to protect against provider abuses.

- Social Security Administration - Improvement will be made in State administration and management of the AFDC programs and increasing the level of child support collections.

## Labor/HHS
## Consulting Services and Related Services

($ in thousands)

| Account | Consulting Services 1984 | Consulting Services 1985 | Related Services 1984 | Related Services 1985 | Total 1984 | Total 1985 |
|---|---|---|---|---|---|---|
| PHS | | | | | | |
| HRSA, Health Resources and Services | $4,162 | $2,079 | $532 | $357 | $4,694 | $2,436 |
| CDC, Disease Control | 1,405 | 1,405 | 762 | 762 | 2,167 | 2,167 |
| National Institutes of Health: | | | | | | |
| National Cancer Institute | 4,590 | 4,754 | 447 | 404 | 5,037 | 5,158 |
| Natl. Heart, Lung, & Blood Institute | 4,836 | 4,918 | -- | -- | 4,836 | 4,918 |
| Natl. Institute of Dental Research | 344 | 395 | -- | -- | 344 | 395 |
| Natl. Institute of Arthritis, Diabetes, Digestive & Kidney Diseases | 2,448 | 2,631 | -- | -- | 2,448 | 2,631 |
| Natl. Institute of Neurological and Communicative Disorders and Stroke | 1,803 | 1,834 | -- | -- | 1,803 | 1,834 |
| Natl. Institute of Allergy and Infectious Diseases | 1,528 | 1,520 | -- | -- | 1,528 | 1,520 |
| National Institute of General Medical Sciences | 2,050 | 2,098 | -- | -- | 2,050 | 2,098 |
| National Institute of Child Health and Human Development | 1,298 | 1,359 | -- | -- | 1,298 | 1,359 |
| National Eye Institute | 710 | 721 | -- | -- | 710 | 721 |
| Natl. Institute of Environmental Health Sciences | 769 | 804 | 56 | 31 | 825 | 835 |
| National Institute on Aging | 674 | 727 | -- | -- | 674 | 727 |
| Research Resources | 885 | 907 | -- | -- | 885 | 907 |
| J.E. Fogarty International Center | 242 | 382 | 2,402 | 2,417 | 2,644 | 2,799 |
| National Library of Medicine | 416 | 443 | -- | -- | 416 | 443 |
| Office of the Director | 7 | 7 | -- | -- | 7 | 7 |
| SUBTOTAL, NIH | 22,600 | 23,500 | 2,905 | 2,852 | 25,505 | 26,352 |
| ADAMHA, Alcohol, Drug Abuse, and Mental Health | 7,315 | 7,665 | 16,987 | 16,398 | 24,302 | 24,063 |
| ADAMHA, Federal Subsidy for St. Elizabeths Hospital | 575 | 1,175 | --- | --- | 575 | 1,175 |
| OASH, Public Health Service Management | 1,103 | 1,103 | 13,280 | 13,000 | 14,383 | 14,103 |
| SUBTOTAL, PHS | 37,160 | 36,927 | 34,466 | 33,369 | 71,626 | 70,296 |

($ in thousands)

| Account | Consulting Services |  | Related Services |  | Total |  |
|---|---|---|---|---|---|---|
|  | 1984 | 1985 | 1984 | 1985 | 1984 | 1985 |
| HCFA, Program Management | 3,807 | 4,384 | 9,512 | 9,940 | 13,319 | 14,324 |
| SSA |  |  |  |  |  |  |
| Assistance Payments Program | 1,450 | 1,450 | 1,252 | 1,252 | 2,702 | 2,702 |
| Child Support Enforcement | 1,165 | 1,165 | 366 | 366 | 1,531 | 1,531 |
| Low Income Home Energy Assistance | 200 | 200 | --- | --- | 200 | 200 |
| Limitation on Administrative Expenses (LAE) | 3,258 | 1,888 | --- | --- | 3,258 | 1,888 |
| ORR, Refugee and Entrant Assistance | 100 | 105 | 1,000 | 1,000 | 1,100 | 1,105 |
| TOTAL, SSA | 6,173 | 4,808 | 2,618 | 2,618 | 8,791 | 7,426 |
| OHDS, Human Development Services | 1,328 | 1,325 | 305 | 240 | 1,633 | 1,565 |
| DM |  |  |  |  |  |  |
| General Departmental Management | 9,582 | 9,406 | 3,267 | 1,860 | 12,849 | 11,266 |
| Office of the Inspector General | 45 | 45 | 2,000 | 3,500 | 2,045 | 3,545 |
| Office for Civil Rights | 133 | 140 | --- | --- | 133 | 140 |
| SUBTOTAL, DM | 9,760 | 9,591 | 5,267 | 5,360 | 15,027 | 14,951 |
| TOTAL, HHS | $58,228 | $57,035 | $52,168 | $51,527 | $110,396 | $108,562 |

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### HIRING SCHEDULE C's IN THE OFFICE OF THE SECRETARY

Question: Secretary Heckler, you plan to reduce the number of full time equivalent positions in the Office of the Secretary by 1,264 -- from 4,342 in FY 1983 to 3,078 positions in FY 1985. Apparently transfers and attrition, particularly as a result of a hiring freeze instituted in August of 1983, have decreased the number to be fired to 350 or less.

Have you hired any Schedule C employees since the institution of the hiring freeze in August of 1983? If so, could you state how many?

Answer: I have hired only 15 persons under Schedule C authority in the Office of the Secretary since I announced the hiring freeze last August. I also made four non-career SES appointments in the same time period. However, we have also lost 20 people under those kind of appointment authorities since last August. Thus, we have experienced a minor "lapse" in these positions.

Question: Do you plan to hire any more Schedule C employees between now and FY 1985, that is, during the period when the total number of employees in the Office of the Secretary is to be reduced?

Answer: I do intend to fill such critical top-level vacancies as the positions of Under Secretary and Assistant Secretary for Legislation. However, I will restrict any Schedule C hires to critical need areas.

Question: Are Schedule C employees included in calculating the total number of full-time equivalent positions in the Office of the Secretary for purposes of determining how many staff reductions are necessary?

Answer: Schedule C positions are included in the calculations and in all personnel charts submitted with our budget requests. As we looked at specific functions in our management review of the Office of the Secretary, we made our decisions on the functions to be eliminated and the number of positions to be reduced with no regard to whether they were filled with career or non-career employees. Our streamlining plans include both career and non-career positions.

Question: Is it not true that your hiring of Schedule C employees, assuming that they are not separated before September of 1984, will increase the number of Civil Service employees who must be fired in September of 1984?

Answer: I want to assure you that we will not be hiring Schedule C employees at the expense of separating career civil servants.

### GRANT-RELATED INCOME

Question: Secretary Heckler, on February 10 the General Accounting Office came out with a report concluding that income earned by HHS grantees was not being used properly in many instances because of inadequate oversight by the Department.

The GAO found that grantees were failing to report income and that unreported income totaled $13.4 million over a two-year period.

To your credit, you concurred in a number of the GAO recommendations and plan to amend your Department-wide grants administration regulations accordingly.

When will the amended regulations be in place?

Answer: We will amend our regulations following an interagency review that OMB is currently conducting of OMB Circular A-102. That circular contains the government-wide grant-related income policies and other grants administration policies that our regulations implement.

As part of the review, agencies are addressing the issues GAO raised in its report to HHS and in a similar report to OMB. We are taking an active part in this review.

We cannot estimate how long the review and revision will take. In the meantime, to improve the reporting of grant-related income, we are taking action to amend the grant financial reporting forms our grantees submit to us.

For your information, of the $13.4 million in audit findings cited by GAO, we have determined that at least $11.5 million was not income in a sense pertinent to the GAO report.

INTEREST EARNED BY GRANTEES

Question: The GAO grant-related income reports identified about $1 million of interest earned on Federal funds that was not reported or returned to HHS. The Department responded that its operating components have concurred in $959,475 of these findings and, subject to appeal by the grantees to your Grant Appeals Board, are taking action to obtain this amount. How much of the $959,475 has actually been recovered?

Answer: Our records indicate that we have recovered all but $3,729 which is under negotiation.

Question: How long do you estimate it will take to recover these funds?

Answer: Generally, under procedures we are not putting into place, we collect these kinds of debts within 30 days from the date of written notification to the grantee that the grantee owes us money.

The specific procedures are:

o An awarding office makes a final determination, based upon an audit, that the grantee owes us money, notifies the grantee, and gives the grantee 30 days to pay.

- o We charge interest on any amount not paid within the 30-day period.
- o If the grantee appeals the determination, the grantee need not pay while the appeal is pending.
- o Interest charges, however, continue to accrue while the appeal is pending. If the appeal is unsuccessful, the grantee must pay the interest as well as the principal portion of the debt.
- o In cases of hardship, we negotiate an extended payment plan with the grantee to pay the debt, including interest.

Question: Based on past experience, what portion of these claims will be denied by the Appeals Board?

Answer: All findings appealed with interest charges have been decided in favor of the Department by the Grant Appeals Board. One claim of $788,000 was litigated after the Appeals Board decided in favor of HHS. The Court sustained the Appeals Board's decision.

## DEBT COLLECTION

Question: The Department had reduced its delinquent debt to $699 million as of the second quarter of fiscal year 1983 from a delinquent debt of $1.1 billion at the beginning of FY 1982. How much delinquent debt is currently outstanding?

Answer: The Department had $606 million in outstanding delinquent debt as of December 31, 1983.

Question: We were informed last year that procedures were being developed to notify credit bureaus of delinquent debtors under those programs having such authority. Are you currently notifying credit bureaus of delinquent debtors?

Answer: In February 1984, the Department published a notice in the Federal Register of its intent to notify credit bureaus of delinquent debtors. The Administrator of General Services is in the process of awarding contracts with credit reporting agencies on behalf of HHS and other agencies for the disclosure of commercial and consumer credit information. When these contracts are in place, HHS will begin to notify credit bureaus of delinquent debtors. All individual debts and debts owed by business concerns to the Department that exceed $100, except debts owed by beneficiaries, will be reported to credit reporting agencies.

## HEALTH SERVICES RESEARCH

Question: HCFA is requesting $35 million for research. The National Center plans to spend $17.3 million for health services research next year. Please tell us where HCFA's responsibilities end and the Center's begin.

Answer: The National Center is the principal support for basic research studies of a general nature on the delivery, financing, and administration of health care services. The Center seeks to develop a better understanding of the processes by which health care services are made available and how they may be provided more efficiently, more effectively, and at a lower cost. An important focus of this research is the development of new ideas for structural reform in the health care system, including alternative health care delivery methods and cost-saving measures within hospitals. Other research looks at services delivery for the disadvantaged, changes in health manpower needs, and issues regarding the quality of care. As examples, NCHSR recently completed a study on the effect of reduced Medicare payment rates on physician practices and a study on the relation between home health and nursing admissions. Many projects done by the Center also demonstrate how improvements in health service delivery can reduce the cost of care (i.e., unnecessary x-rays, more effective cardiac units, generic drug substitution). In addition, NCHSR is responsible for technology assessment activities in the Department and in assisting HCFA in making decisions on Medicare coverage issues. Examples of technology assessments include: renal dialysis for schizophrenia, heart pacemakers, and home blood glucose monitors for diabetics.

HCFA, in contrast, conducts applied research studies oriented toward improving the efficiency of Medicare and Medicaid expenditures. HCFA research is highly program relevant and focused on management, regulatory, and legislative improvements in the two programs it administers. The bulk of current research is looking at the impact of the recently enacted Prospective Payment system on hospitals and at ways to extend the system to other segments of the health care system. More specifically, HCFA is, for example, examining ways of incorporating capital and outpatient services in the prospective payment system and alternative methods of reimbursing physicians under Medicare. In the past, HCFA's research efforts have led to program reforms which resulted in significant savings to Medicare and Medicaid, such as elimination of the routine nursing salary differential and reductions in malpractice payments.

We fully recognize the interrelationship between the research programs of the agencies, and to avoid duplication of research effort we have encouraged coordination and cooperation at the planning and project development stages. Duplication is avoided through required exchange of annual plans and through plan review and oversight by the Office of the Secretary.

Question: Do you have a mechanism in place to insure that HCFA is not duplicating research being supported through the Center? If so, describe it.

Answer: There are three mechanisms for avoiding duplication. First, in the Spring of each year, every research program in the Department reviews its research strategy and prepares a revised plan. These plans identify changes in research emphasis and direction, and describe major initiatives. Plans are exchanged among appropriate agencies and are reviewed by the Office of the Secretary in conjunction with the development of the budget request. Second, project staff are encouraged to consult broadly in the development of a new project. Such consultation not only involves staff from the two research programs but from the operating programs and outside researchers as well. Finally, systems have been established to exchange information on grant applications, and personnel from the Center often sit on HCFA project review panels.

## HEALTH SERVICE RESEARCH

Question: When Dr. Brandt appeared before this Committee on Monday, his opening statement referred to the work of the National Center for Health Services Research (NCHSR) in these words: "NCHSR funds provided for the original work on Diagnosis Related Groups (DRGs), that is, the development and testing of homogeneous patient classes from the perspective of resource consumption." On the other hand, the Health Care Financing Administration justifications had this to say in describing a request for $35 million in research, demonstration, and evaluation funds: "Research activities developed the per case payment methodology for the prospective payment system based on a diagnosis related groups (DRGs) approach." Can you tell us who did what in the area of DRG research?

Answer: NCHSR funded a major research project by Yale University in 1969 to examine alternative methods of measuring outputs at hospitals. This research, conducted between 1969 and 1976, examined case mix and alternative funding mechanisms and established the base for the concept of DRGs. The group concept and the technology that was necessary to look at variations in resource consumption were established through this early research.

HCFA conducted the early tests and demonstrations to determine the feasibility of applying the DRG concept to hospitals and developed the system and data base needed to implement the Medicare prospective payment nationwide. At the request of the Congress, HCFA is now looking at the impact of Prospective Payment on hospitals and at ways to extend the DRG concept to other segments of the health care system. Current activities are devoted to demonstrations to test proposed changes in reimbursement mechanisms, changes in coverage eligibility, and new management approaches.

Question: Dr. Brandt indicated in his opening statement that the Center's work "will be essential in assessing the impact of the DRG prospective payment system." HCFA's justifications make reference to the Center, but characterize its work as having a "secondary application" to HCFA programs. Can you reconcile these two statements?

Answer: The Center conducts research on the health care system generally; particularly on the structure, organization, and behavior of health resources. Since the change to Prospective Payment of hospital services under Medicare will inevitably affect all aspects of health care, the Center will study the overall impact and, in particular, the impact on the demand for, and supply of, health resources and the implications of Prospective Payment for projecting future resource needs, both public and private. Not only is it important that HCFA be aware of the direct effects of prospective payment on the Medicare system, which it studies, but it must be aware of these "secondary" effects as well.

## QUESTIONS SUBMITTED BY SENATOR LAWTON CHILES

### COMMUNITY SERVICES BLOCK GRANT FUNDS FOR FLORIDA

Question: Governor Graham of Florida asked the President to declare a major disaster for Florida as the result of the severe freezing temperatures we experienced in December. Five counties were the hardest hit. In addition to disaster unemployment assistance, the Governor requested a supplemental allocation of Community Services Block Grant funds of $585,000 to provide emergency food and shelter.

I understand you have received this request for the block funds. How is the Department responding?

Answer: Governor Graham has requested that the CSBG allocation for Florida be increased by $585,000 to provide emergency food and shelter in counties affected by the damage to citrus crops caused by freezing weather last December. This assistance would be in addition to that already provided through normal disaster assistance channels under P.L. 93-288, the Disaster Relief Act of 1974. We have advised the Governor that all of this year's CSBG funds have been allocated according to the formula set out in the statute. Because the CSBG is a formula grant, there is no way under current law to transfer funds among the States to accommodate such disasters. Therefore, the Federal Emergency Management Agency (FEMA) is the appropriate agency to handle this situation.

Question: I know the Administration is not requesting any Community Services Block Grant funds for 1985. Are all the 1984 funds already allocated, are they going to be all used in the fourth quarter, or will there be some "carry-over" funds?

Answer: Twenty-five percent ($79.2 million) of the CSBG funds will be made available to States in the fourth fiscal quarter. This allocation will be made according to the CSBG formula required by law, and once this is accomplished, 100 percent of the block grant funds will have been obligated in FY 1984.

States are allowed two years in which to expend their CSBG funds, and Florida and other States may carry FY 1984 CSBG funds into FY 1985. However, such funds are not transferable to other States.

Question: Are there anticipated to be any left-over funds suitable for reprogramming from other programs? Or will Congress need to pass a supplemental for the Community Services Block Grant for Florida to get this?

Answer: Only funds within an appropriation may be reprogrammed and, as stated above, the CSBG formula would not permit reallocation of funds within the block. In addition, the Congress has provided certain discretionary funds within the CSBG appropriation; however, those funds were earmarked for specific purposes by the Congress and, in our judgment, are not susceptible to reprogramming action.

States do have the option to transfer funds among certain other block grants. However, only the Low-Income Home Energy Assistance Program (LIHEAP) can transfer to the CSBG. Funds for the LIHEAP are also obligated at the Federal level according to a legislatively mandated formula which does not permit reallocations among the States based on other criteria.

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## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### NIMH POSITION REDUCTIONS

Question: It is my understanding that you are considering a plan to implement a Reduction-in-Force (RIF) at NIMH that will eliminate the Division and offices responsible for administering the clinical training and the community support programs and that the staff now working in these areas will be reduced by 70 percent. Yet, it is also my understanding that the overall reduction-in-force at NIMH will represent only a 7 percent decrease in total staff (going from 1,045 to 981). Further, the document proposing the 70 percent reduction in the clinical training and community support staff states that "this action will result in a major problem for the Institute if Congress reinstates these programs." The Committee is especially concerned that the NIMH retain its ability to target funds to truly unique areas, such as minorities.

First, I would like to hear your thoughts on the rationale for taking the approach just outlined, given that this Committee and the Congress have funded these programs each year the Administration has proposed to eliminate them and in view of there being every indication that Congress will do so again this year.

Answer: The allocation of personnel within all ADAMHA programs was based on programmatic need, the need to compensate for an employment overage situation which has existed in certain areas of ADAMHA for several years, and the need to reduce overall staff consistent with the Administration's goal of reducing overall Federal employment. The selection of the clinical training and community support programs for major reductions is consistent with proposals for the phasing out of programs. The President's budget has been carefully developed to match resource requirements, both in terms of dollars and personnel, with the programs proposed in the budget request. In light of the Federal deficit, we have allocated resources on a programmatic basis in a judicious manner; little flexibility exists to staff programs not conceived by our request. Staff assigned to other NIMH programs were also allocated in an efficient manner which emphasizes the goals of the President's budget, including the maintenance of a stable, consistent research program. To reallocate staff from these programs to programs proposed for elimination in 1985 will inhibit our ability to achieve these goals.

### STAFFING ADEQUACY

Question: Secondly, I would like to know what steps you will take to insure that these programs will be effectively administered, assuming that they are reinstated by the Congress. Specifically, I would like you to respond to the suggestion in the current proposal that a staff reduced by 70 percent, bringing the number of staff to administer the clinical training program to four, for example, is workable or reasonable.

Answer: What will have to be done is either to redirect personnel needed in other areas, such as the extramural research and research training programs, or to continue to retain some personnel with skills in these areas at the expense of the above programs in order to help accomplish the task requested by the Congressional add-on. How this will work precisely depends on the size and requirements of the Congressional add-on, but it will impact adversely upon the higher priority programs of the institute.

## JOINT NIMH/NIH AIDS PROJECTS

Question: The Committee is interested in learning of any plans which the NIMH may have to address the psychosocial aspects of AIDS. Particularly, the Committee is interested in learning to what extent NIMH and NIH are planning on developing joint projects during this or the next fiscal year.

Answer: In FY 1983, NIMH sponsored two research planning workshops focused on psychological, behavioral, and psychoneuroimmunological factors related to the acquired immunodeficiency syndrome. The first explored research strategies which may be useful in addressing psychological factors such as stress and coping, the mental health impact on vulnerable groups, and behavioral factors. Participants included non-Federal scientists in the areas of immunology, psychiatry, psychology, nursing, medical sociology, and epidemiology as well as intramural scientists from NIMH, the National Cancer Institute, and staff of the Clinical Center at NIH who are conducting research with AIDS patients.

The second workshop addressed concerns among the public and health caregivers. Participants included psychiatrists, psychologists, health policy experts, and public education experts from different parts of the country. Representatives of several Public Health Service offices also participated.

In addition, NIMH funded three studies of psychosocial factors associated with AIDS. In FY 1984, NIMH is in the process of funding three additional projects which focus on the psychosocial and behavioral aspects of AIDS. Among additional projects awaiting review and funding, are two which will collaborate with the ongoing National Institute of Allergy and Infectious Diseases funded multi-center contracts. Finally, plans are underway for a workshop which would involve currently funded NIMH AIDS grantees in discussions of methodologies and collaborative efforts with NIH.

## STAFFING AFTER PROGRAM RESTORATIONS

Question: A GAO report that was requested by the Congress, which has not yet been released, found that the present staff of 11 professionals in clinical training was inadequate to do the necessary review of grants and that the alternative of using individuals from throughout the Institute was inefficient. Further, the report suggests that present staffing levels are inadequate to evaluate whether or not professionals are making their way to the underserved areas outlined by this Committee as well as unable to appropriately follow-up on the payback provision.

In light of these indications that present staffing levels are pressed to the limits, and beyond, is it reasonable for the Administration to propose such a disproportionate (70 percent vs 7 percent) RIF in this area. It strikes me that the plan under consideration is an attempt to dismantle the clinical training and community support programs by staffing reductions despite what this body decides to do in terms of funding. Can you assure this Committee that if we fund these programs that the Institute will commit itself to carrying out the mandate of Congress in this area? If this Committee is unpersuaded that the current proposal is incapable of carrying out the mandate of these two programs, will you be willing to consider alternative proposals that weigh less heavily in these areas?

Answer: The plan under consideration is not an attempt to surreptitiously dismantle these programs. We have already proposed the straightforward elimination of them. This plan simply reflects our approach to responsively match the resources available to us with the programs to be supported in the President's budget. This budget has been carefully designed to provide only the personnel absolutely necessary to operate its designated programs and we are applying appropriate measures to realize this aim.

Should Congress not accept our proposal we will have to either redirect personnel needed in other areas, such as the extramural research and research training programs, or to continue to retain some personnel with skills in these areas at the expense of the above programs in order to help accomplish the task mandated by the Congressional add-on.

## CENTERS FOR DISEASE CONTROL

**STATEMENT OF JAMES O. MASON, DIRECTOR**

**ACCOMPANIED BY:**

**WALTER R. DOWDLE, DIRECTOR, CENTER FOR INFECTIOUS DISEASES**
**ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator WEICKER. We are pleased to welcome Dr. James Mason, who is making his first appearance before our committee as CDC Director.

We certainly wish you well in your new responsibilities. Dr. Mason, you can go right ahead and introduce your colleagues and proceed with your testimony.

[The statement follows:]

## STATEMENT OF DR. JAMES O. MASON

Mr. Chairman and members of the Committee: It is an honor for me to be appearing before you for the first time as the Director of the Centers for Disease Control (CDC). I am here to support the 1985 fiscal year budget request for the Disease Control Appropriation, which is the principal funding source for CDC. Next year we need $280.4 million and 3,890 FTE's in our effort to prevent avoidable illness, suffering, and premature death. Going through intensive briefings as the new Director of CDC, one has to be impressed with the scope and complexity of CDC's operations and certainly with its record of accomplishments. I would like to share with you some of the highlights.

### IMMUNIZATION

The 1990 Objectives for the Nation, which were established in 1980, set specific levels of immunization for school age children. With six years to go, the Nation has exceeded these levels and disease incidence has reached all time lows. For example, in 1983 only 4 percent of the more than 3,000 counties in the United States reported measles cases. The Childhood Immunization Initiative has been a success and now our program is concentrating on raising the immunization levels of preschoolers. We have begun to build a vaccine stockpile to serve as a national backstop in case of emergencies caused by the interruption of vaccine supplies. However, one challenge, in particular, remains before us. Each year it is estimated that more than 100 cases of Congenital Rubella Syndrome occur. The burden of each of these tragedies extends beyond the individual and the family to the community; with each case there is an estimated lifetime cost of more than $220,000. Unless we act vigorously, we expect that preventable exposure to rubella of susceptible pregnant women with continued affliction of children with its devastating effects will continue for at least 15 more years. In our 1985 budget request, we are proposing an increase of $2 million to initiate a rubella elimination strategy which will include special efforts to immunize women of childbearing age to hasten the elimination of Congenital Rubella Syndrome. (CHART 1)

Since the authorization for the immunization grant program expires in 1985, we are requesting an extension of that authority for an additional three years.

## SEXUALLY TRANSMITTED DISEASES

An estimated 10 million cases of Sexually Transmitted Diseases (STD) occur each year, primarily in adolescents and young adults. At least 23 organisms and 26 syndromes are now recognized as being sexually transmitted. The number of reported cases of gonorrhea declined by nearly 7 percent during 1983 and there was a reduction of more than 5 percent in the number of reported cases of penicillin-resistant gonorrhea--the first reduction since the organism was introduced into this country in 1976. Reported incidence of primary and secondary syphilis decreased in 1983 by 0.3% below cases reported in 1982, which is the first decline since 1976. However, the rate among women increased by more than 4 percent, which heightens our concern about congenital syphilis. The additional funds provided by Congress for 1984, and continued in 1985, will be used, in part, for efforts aimed at reversing this trend. (CHART 2)

To learn more about herpes, CDC is collecting nationwide information about neonatal herpes in an effort to define the extent of the problem in the United States, and is collaborating with the National Institutes of Health and Emory University to define the epidemiology and natural history of genital herpes simplex virus. And, I am pleased to report that we will be evaluating two diagnostic tests for chlamydial infections recently approved by the Food and Drug Administration. If they prove to be effective, diagnosis of the disease will no longer be an obstacle to practical public health control efforts.

A legislative proposal is being submitted that would extend the authorization for the sexually transmitted diseases grant program for three years.

## INFECTIOUS DISEASES

Acquired Immunodefiency Syndrome (AIDS) continues to grow as a public health problem. As of February 13, 1984, there were 3,452 reported cases and 1,488 deaths attributed to AIDS since June 1981. We know much more about AIDS than we did a year ago. Epidemiologic data have shown AIDS to be caused by an infectious agent. Risk groups are better identified. On the other hand, we have not identified the agent. While laboratory work by CDC and others has lead to increased understanding of the disease, efforts are being expanded to verify and characterize the etiologic agent for AIDS, with particular emphasis on human T-cell leukemia virus and other retroviruses. Additionally, we will continue to improve surveillance programs in concert with State and local health departments to clarify risk factors and to provide prevention recommendations and other timely information to public, scientific, and public health communities and high risk groups. The 1985 budget includes $12.0 million for the CDC AIDS activities, as part of the $53.9 million requested throughout the Public Health Service to combat AIDS.

In 1984 and 1985, we will be speeding up application of the molecular biology technology and hybridoma cell culture in order to take advantage of this technology development that holds such promise for improving the accuracy and rapidity of disease diagnosis and vaccine development. (CHART 3)

## CHRONIC AND ENVIRONMENTAL DISEASE PREVENTION

There are numerous health activities supported in this part of our budget. For example, we have one of a kind chemistry laboratories that are applying state-of-the-art technology to meet the growing need for rapid, accurate identification of hazardous substances in our environment. We are continuing studies and surveillance of birth defects. This program produced convincing evidence of the association between the use of the anticonvulsant drug valproic acid during pregnancy and the occurrence of spina bifida. Working collaboratively with the National Park Service we have successfully prevented any food or waterborne disease outbreaks among the 245 million visitors to the Nation's national parks since 1983. To address health problems associated with personal health behavior, such as stress, smoking, and alcohol abuse, we conduct research and evaluation of health promotion programs, surveillance of risk factors, and provide technical assistance and training to State and local health agencies.

Two major activities, not funded from this Appropriation, deserve mention at this point. CDC continues to have the lead in the Department for implementation of HHS responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund). These activities are funded under an interagency agreement with the Environmental Protection Agency. The workload continues to rise. In 1983, we provided EPA approximately 780 health consultations regarding health issues at Superfund sites and have provided 358 emergency responses. As a result of our participation in Superfund, there is now a source of medical and laboratory advice available to State health and environmental officials, hospitals and private physicians, and citizens who may have been exposed to hazardous substances. For instance on October 13, 1982, when a truck overturned at 1:30 a.m. in Odessa, Delaware, spilling toxic compounds of benzene, CDC physicians were available to consult with local officials on the care and treatment of exposed emergency personnel and clean up crews. We also provided advice on how citizens should be protected (CHART 4)

Under an interagency agreement with the Veterans Administration (VA), CDC is responsible for all phases of the Agent Orange epidemiologic study. Congress appropriated $54.0 million to the VA last year for CDC to carry out the study. Scientific reviews of the protocol by the Office of Technology Assessment and the Science Panel of the Interagency Agent Orange Working Group were completed in September 1983. Pilot tests are underway, with the cooperation of the Department of Defense and other agencies, to identify and locate qualified participants for this study.

## OCCUPATIONAL SAFETY AND HEALTH

An essential part of our prevention mission is to protect the health and safety of American workers by conducting research and applying research results to prevent illness and to control hazards in the workplace. CDC's

National Institute for Occupational Safety and Health (NIOSH) approaches this task by: (1) identifying work related diseases and injuries through its surveillance and health hazard evaluation activities; some important findings deal with PCB fires, hazardous waste dumps, and silicosis in foundries; (2) evaluating work-related diseases and injuries and hazards, particularly through research targeted toward the Ten Leading Work-related Diseases and Injuries; (3) developing, assessing, and improving measures to reduce hazards such as the guidelines on pesticides manufacturing and handling; and (4) disseminating scientific findings and appropriate recommendations to organizations and individuals with an interest in occupational safety and health and assisting them in acting to reduce work-related disease and injuries. Of particular interest to me, as a former State Health Officer, is the special effort that is being put into defining effective health promotion in the workplace and for seeking greater participation of State and local health departments in the Nation's occupational safety and health endeavors. For example, the Conference of State and Territorial Epidemiologists, in response to our encouragement, has agreed that silicosis should be added to the list of diseases reported weekly to CDC.

## EPIDEMIC SERVICES

CDC conducts active disease surveillance, operates the Epidemic Intelligence Service, performs diagnostic reference service activities, and carries out quarantine responsibilities. These activities allow CDC to identify and respond quickly to unexpected disease problems.

We are working closely and actively with other Federal agencies, as well as State and local governments, to prepare for health emergencies that might occur during the summer Olympics in Los Angeles.

We are working with the Los Alamos Laboratories to apply advanced technology to the development of new procedures which would permit the rapid and reliable detection of organisms and toxic chemicals in both field and clinical settings.

We are in the process of implementing a Prevention Research and Development Program. I see this as a way of enlisting the aid of medical and public health schools, health departments, and other organizations and stimulating innovative thinking toward the solution of infectious disease, chronic disease, or environmental health prevention problems.

## OTHER BUDGET CHANGES

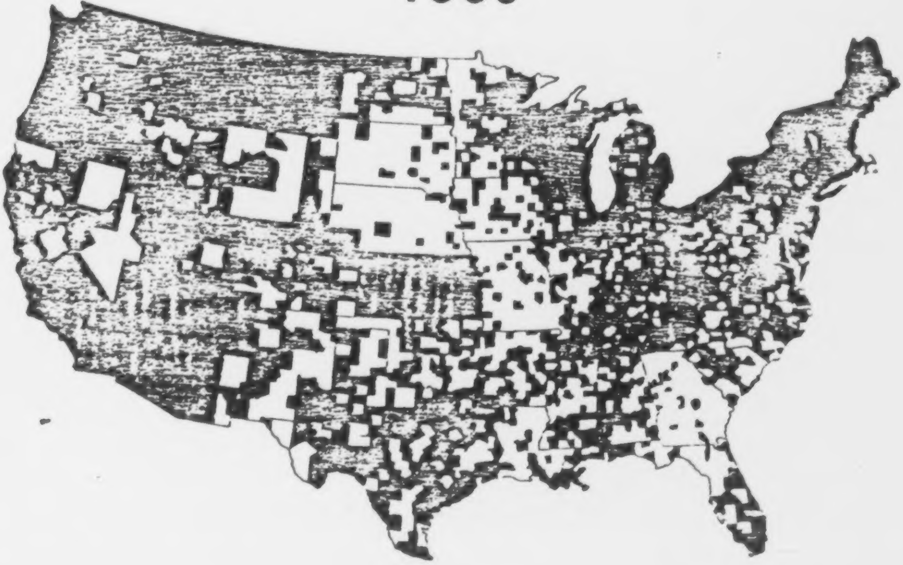
For 1985, the Preventive Health Services Block Grant has been consolidated with other block grants in an appropriation to be administered by the Assistant Secretary for Health. Categorical grant funding is not necessary for tuberculosis control since block grants and refugee preventive health programs already cover this activity. Since State programs for fluoridation and childhood lead poisoning prevention are carried out with block grant or other funds, no funding is requested for federal staffing. Funds are no longer requested for occupational safety and health training, which has been a successful demonstration program now more appropriately funded by non-Federal sources. Also, as recommended by GAO, CDC will charge a user fee in fiscal year 1985 for reference diagnostic services provided to State health department laboratories.

I will be happy to answer any questions that you may have.

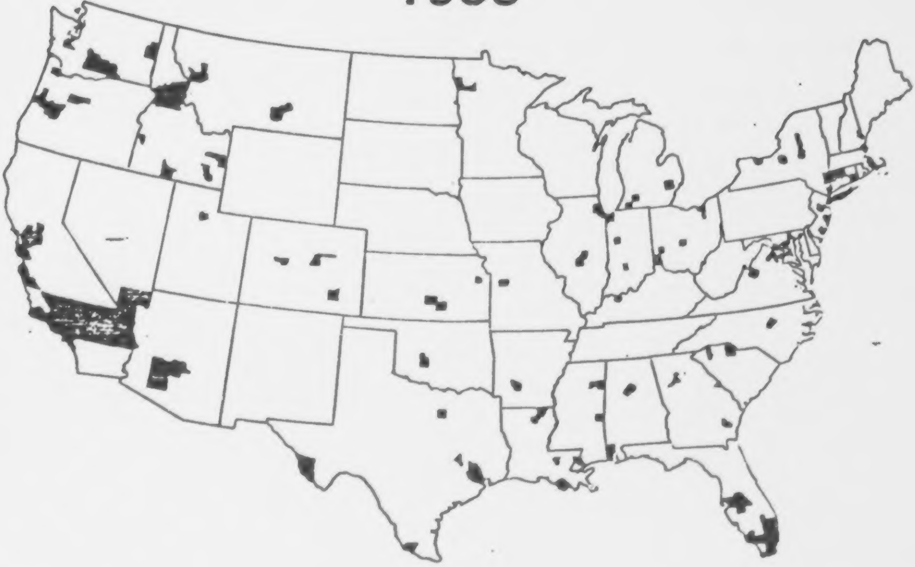
Case #1

# COUNTIES REPORTING MEASLES

## 1960

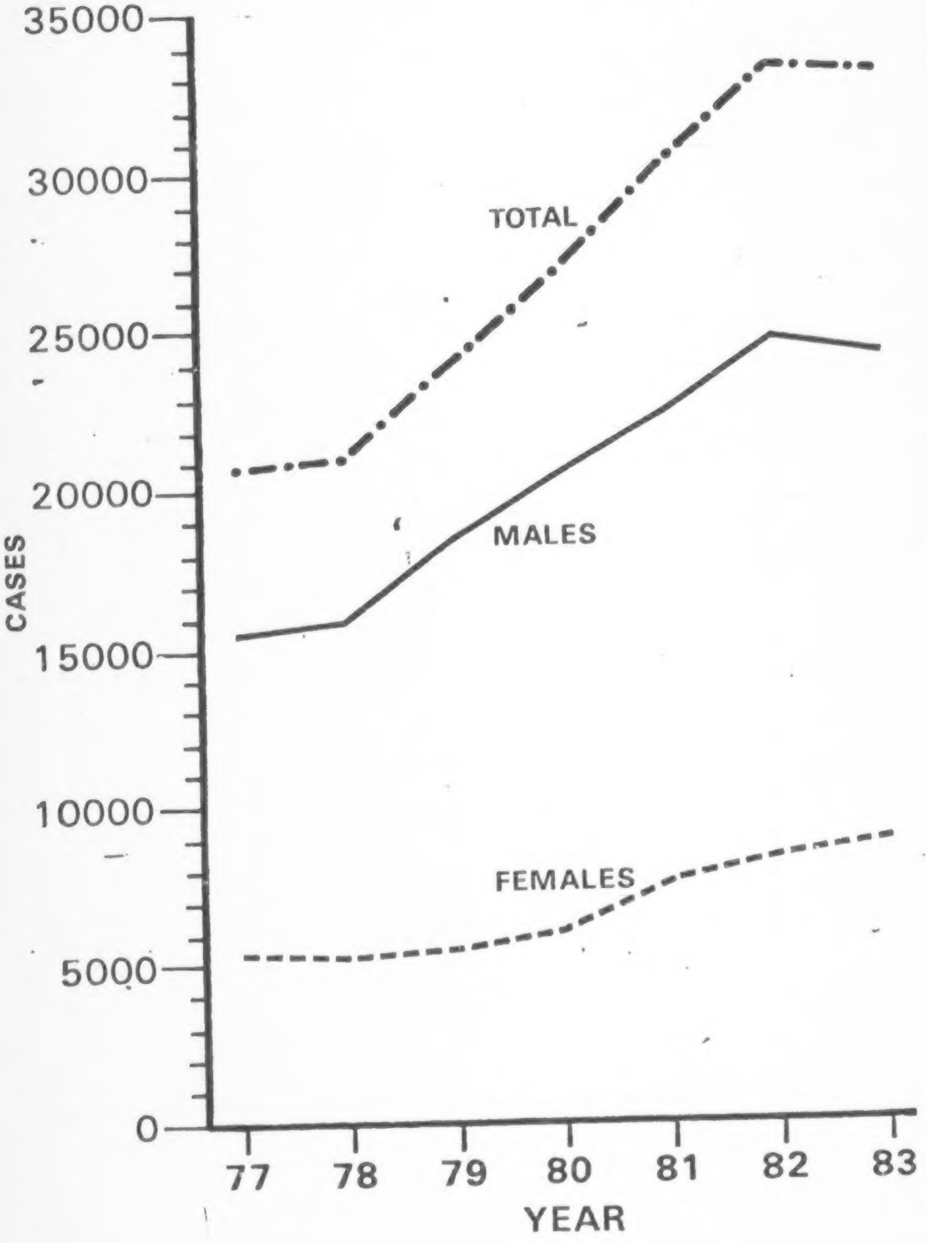


## 1983

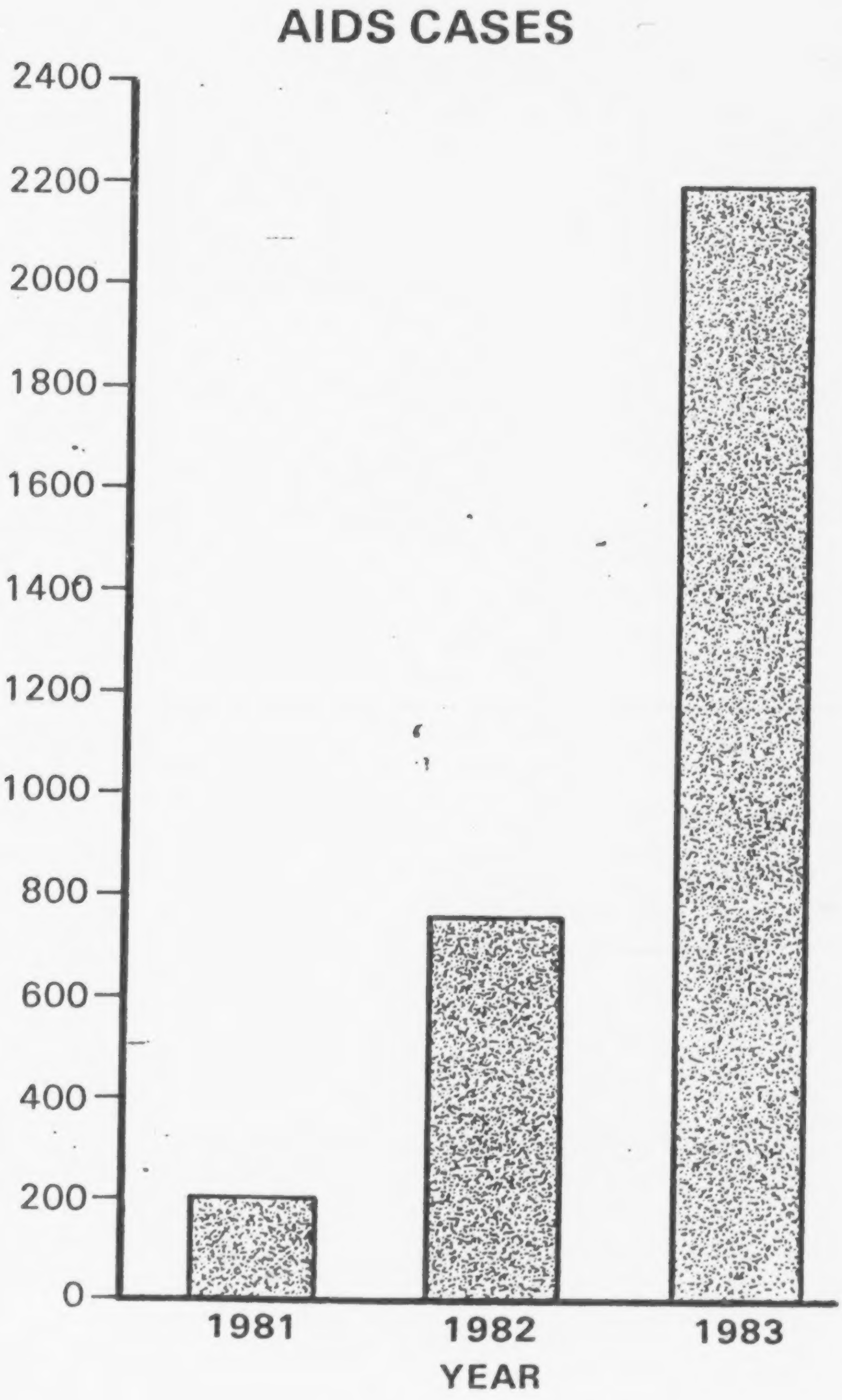


Case #2

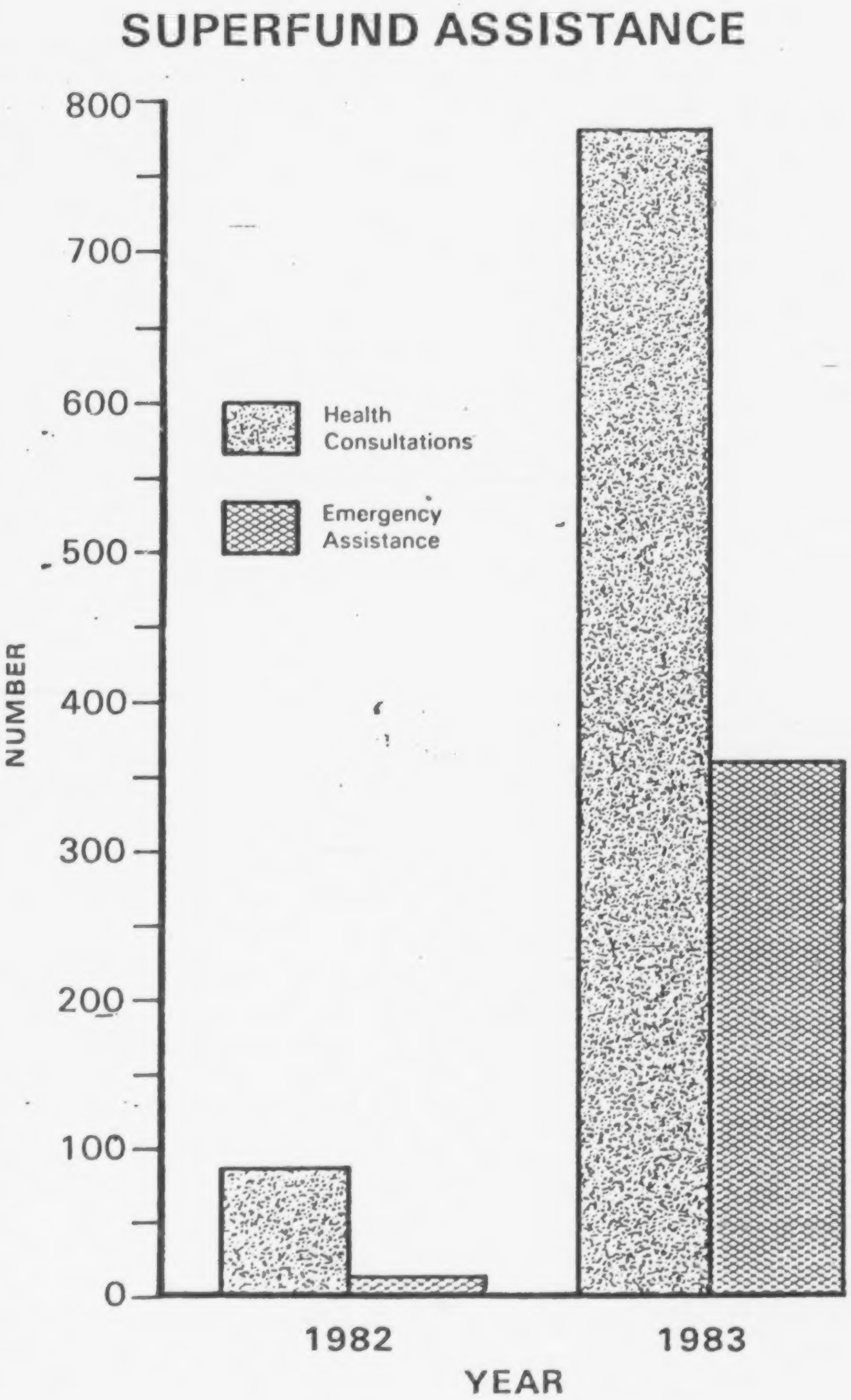
# PRIMARY & SECONDARY SYPHILIS



Case #3


AIDS CASES
2400
2200
2000
1800
1600
1400
1200
1000
800
600
400
200
0
1981
1982
1983
YEAR

Case #4


SUPERFUND ASSISTANCE
800
700
600
500
400
300
200
100
0
NUMBER
Health Consultations
Emergency Assistance
1982
1983
YEAR

### INTRODUCTION OF ASSOCIATES

Dr. MASON. Thank you, Mr. Chairman. I have on my right Mr. Tony Itteilag, and you know him; on my left is Dr. Walt Dowdle, who is the Director for the Center for Infectious Diseases. Dr. Dowdle has been responsible for the group that has provided solutions for toxic shock and Legionnaire's disease and now is heading up our work on AIDS.

It is an honor for me to be appearing before you for the first time as the Director of the Centers for Disease Control. We miss Dr. Foege there, but we are going to try to provide the same visionary leadership that was provided by him and his predecessors.

I am here to support the 1985 budget for the disease control appropriation, which is the principal funding source for CDC. We have need for $280.4 million and 3,890 full-time equivalents if we are going to promote good health and prevent avoidable illness, suffering, disability, and premature death.

I want you to know that I am impressed with CDC, the accomplishments of its staff, the scope and complexity of its mission. As a former health officer, it's wonderful to be associated with an organization that is providing the leadership that is occurring at CDC.

Briefly I would like to show four charts which exemplify some of the things that are being accomplished as we work to promote health and prevent disease, disability, and death.

### MEASLES

The first one shows reported measles cases in the United States, and it contrasts 1960 with 1983. In 1983 only 4 percent of the Nation's more than 3,000 counties reported measles cases. We are ahead of the objectives for the Nation for 1990 in terms of immunization. New lows have been reached in 1983 for every immunizable disease except pertussis. We are proud of that record. There is still a great deal that must be accomplished.

### SEXUALLY TRANSMITTED DISEASES

Chart 2 on sexually transmitted diseases. By the way we are still having 10 million new cases each year, and we know that as many as 23 different microbiological organisms are recognized as being transmitted by intimate contact. This chart shows primary and secondary syphilis, and for the first time since 1976 there has been a decline in reported primary and secondary cases. Although the overall chart shows a decline, the number of cases has gone up 4 percent for females, and this, of course, gives us concern with regard to reducing the number of congenital syphilis cases in newborn infants.

### AIDS

Chart 3. This chart demonstrates the number of cases of AIDS that have been reported since 1981 in this country. We currently have a total of 3,954 cases, and of these, 1,723 have died. That represents a 43-

percent death rate among these cases, and I think as we go longer in the epidemic we will see even a higher case fatality rate.

We want to report to you that a great deal of progress has been made in the epidemiology of this disease and the high risk groups are very well defined. We are making progress in the laboratory, and we hope to soon have some evidence that a retrovirus is indeed responsible for this disease. That kind of announcement, I think, simply awaits further confirmatory work that is being done collaboratively at CDC, NIH, and the Pasteur Institute in France.

### SUPERFUND

The final chart. Our Center for Environmental Health during 1983 provided 780 health consultations at superfund sites and 358 emergency responses. You can see by the chart the rate of entries in which our health related activities are being requested by the States to help in terms of hazardous waste and toxic waste cleanup.

### NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

In a related area, in 1983 the National Institute for Occupational Safety and Health received 498 requests for health hazard appraisals, which is a 17-percent increase over the previous year. They completed two criteria documents in 1983, and eight are being produced in fiscal year 1984.

### DISEASE PROBLEMS

There are many other successes that I might highlight, but time does not permit it. I should mention that in spite of this progress there are still problems in the United States, such as disease that can be prevented, disability that can be prevented, and premature death that can be postponed. We still have pockets of low immunization in certain communities. We still have congenital rubella syndrome crippling newborns. Herpes infection continues to go up in terms of the number of new cases and more newborns are being afflicted with this tragic disease. We have congenital syphilis. We have cancer of the cervix, which is largely preventable, that kills thousands of women in the United States annually. Smoking remains a major cause of preventable death and disease, and even though some progress is being made with regard to smoking in males, the statistics in females appear to be very disappointing and we are seeing now rising numbers of cancer of the lung associated with more tobacco use in the female population of our Nation.

We will be happy to answer any questions you may have with regard to our appropriation request.

## STAFFING LEVELS

Senator WEICKER. I realize, Dr. Mason, that you are a newcomer to this position and probably were not involved in the formulation of the budget, but I would like to ask you some questions about staff levels.

Your budget documents indicate that total compensable work-years for CDC will decrease in fiscal year 1985 by 172. Is this a decrease in full-time equivalent positions?

Dr. MASON. Yes; that is correct.

Senator WEICKER. Is it your professional position that you do not need the 172 full-time equivalent positions to effectively carry out the various public health functions of CDC?

Dr. MASON. Mr. Chairman, it is my judgment that I will need 4,085 positions and 4,212 full-time equivalents to carry out the functions that are proposed in this budget. This number represents our 1984 level plus 50 positions and full-time equivalents for the Venereal Disease Grant Program added by Congress, 42 positions and FTE's to respond to the increasing number of requests from EPA related to superfund activities, and an increase of 58 positions and full-time equivalents for AIDS related activities.

Senator WEICKER. It is your position that you need 4,212 total?

Dr. MASON. If we are to adequately carry out those responsibilities that are assigned to us.

Senator WEICKER. States receiving CDC grants may opt to receive a portion of their award in the form of positions in lieu of cash. In other words, many choose to receive assistance in the form of actual health professionals on loan to their health departments.

Your justification states that there will be a decrease of 50 positions in lieu of cash available to the States in fiscal year 85 for public health advisers in the Venereal Disease Program. Are these the 50 positions that the Congress added last year?

Dr. MASON. That is correct.

Senator WEICKER. Did CDC actually ever receive the authority for these 50 positions from OMB in fiscal year 1984?

Dr. MASON. No; we did not have the full-time equivalents within our ceiling.

## VENEREAL DISEASE PROGRAM

Senator WEICKER. How has the Venereal Disease Program within the Centers for Disease Control contributed to the prevention, treatment, and control of sexually transmitted diseases?

Dr. MASON. As I mentioned earlier, there are 23 different infectious organisms that are transmitted sexually. Our activities have been broad, with our focus on syphilis, gonorrhea, and to a lesser extent, but growing extent, on herpes and chlamydial infections. In the broad-based program where we have significantly decreased the number of cases there is a drop in gonorrhea, there is a decline in syphilis, and there is a decline in congenital syphilis, but where we are having problems are in the areas of herpes and chlamydial infections.

We conservatively estimate that we have saved over $100 million this year in hosptal costs for pelvic inflammatory disease and other problems in women as a result of the reduction of cases that have occurred as a result of these expenditures.

Senator WEICKER. A study published by the journal of the American Medical Association determined that medical students today are woefully undertrained to deal with sexually transmitted diseases.

Do you agree with this conclusion?

Dr. MASON. Yes; and we have used money that has been appropriated for that purpose to train in medical schools. We hope to do a lot better job in the future in getting into the medical schools and helping them to stay up to date with regard to not only the problems of the past, but today's emerging problems in sexually transmitted disease as a result of changes in lifestyle in our populations.

### VACCINE STOCKPILE

Senator WEICKER. The Department is working toward the goal of maintaining a sufficient stockpile of vaccines. Your budget requests $4 million, the same as the previous year, to increase the duration of vaccine supply from 11 to 16 weeks, which amounts to 60 percent of your stated goal of a 6-month supply.

Why are you not requesting the full amount for a 6-month vaccine stockpile in fiscal year 1985?

Dr. MASON. That is our goal, to have 26 weeks stockpile on hand. There are a number of reasons for going at this at a slower pace. One is to reduce costs in any one fiscal year. Another one is to prevent a large load on the vaccine manufacturers, as they would have to gear up for a bigger vaccine production than would otherwise be necessary. So we have just tried to gradually phase in to that and over a number of years build it up to the 26 weeks.

### AIDS UPDATE

Senator WEICKER. I only have a few minutes left here. I wonder if Dr. Dowdle would like to give us an update without asking specific questions. I think it is much easier to ask him to respond to the general matter of AIDS and where we stand, what is going on, what the problems are, et cetera.

Dr. DOWDLE. Well, first, if I may comment on the epidemiology. As Dr. Mason has pointed out, there are nearly 4,000 cases of AIDS. Interestingly, the patient characteristics are pretty much the same as they were 2 years ago, in that 71 percent are homosexual, bisexual men, and 17 percent are IV drug abusers. Among hemopheliacs, AIDS is becoming one of the most important risk factors for death. AIDS has become a major problem. Also, AIDS is found in some transfusion associated cases, and then finally Haitians and other individuals for which no risk factors have been identified.

The epidemiologic pattern has not changed that much. AIDS is still continuing; however, we have more evidence now that the incubation period is anywhere from 1 to 4 years, depending on the age of the individual and other factors. This means that if it were possible to do something right now to intervene in the transmission, for example, make recommendations regarding blood transfusions, we would still have some period of time before we would see any effect of those recommendations. We have to keep this in mind.

We think our educational efforts have been useful; the recognition of AIDS among those at highest risk of acquiring AIDS is greater, and the public knowledge of AIDS is much greater. In this regard we have come a long way. Although more educational efforts can always be used, the real effort is at the laboratory front to determine the etiology of AIDS. Right now the most promising lead would appear to be what is referred to as a retrovirus. This is a family of viruses which cause leukemia and lymphoma in cattle and horses and primates. It is not an unknown virus, but it has only recently been recognized as being a cause of disease.

The problem is to sort out which of these, not that we consider the animal virus to cause the disease, but which of the human isolates may be the cause of the disease or associated with the disease in humans. We might get a lead from positive laboratory tests with a protein or antigen from one virus which may suggest that that virus may be the cause, but it may in fact be a closely related virus which is the cause.

All of these retroviruses grow in the lymphocytes, even subsets of lymphocytes, so that they are extremely difficult to deal with. Plus, in the case of AIDS, as the disease progresses, fewer and fewer lymphocytes are available to produce the virus. So it's a very difficult problem to reach. Thus, the more advanced the disease, the less likely the virus findings will be positive.

## BLOOD DONATIONS

Senator WEICKER. What about the problem which seems to be getting a great deal of attention, blood plasma or blood donations?

Dr. DOWDLE. It would take some time before we really see the effect of the current voluntary screening, but the general feeling is that the blood banking industry is very much behind screening procedures now. From what few studies have been done and can be done—it is very difficult to do these types of studies—it would appear that there is good cooperation from those populations who may be at risk of acquiring AIDS who have been asked not to give blood.

Senator WEICKER. Is it true that it is possible through apparatus to screen the blood to see whether the virus or the AIDS factor is in there but the machine is very expensive?

Dr. DOWDLE. There really is no direct laboratory test at this present time. Once work is sorted out, there may be a test which can be shown to provide direct evidence of the virus. Right now all tests are indirect. There are a number of indirect tests which could be done, but there is no certainty of the findings and they are also all expensive at this point.

### AIDS SCREENING TEST

Dr. MASON. That is what we are working on, Mr. Chairman. We can do that for syphilis. A few years ago people were getting hepatitis associated with blood transfusions and then we were able to detect hepatitis B virus in blood. And so now there is a screen test done on every blood unit for syphilis and hepatitis B, and if the work that Dr. Dowdle and his colleagues are doing proves to be successful, then we hope that one of the first applications would be a test so that every unit of blood not only would be screened for syphilis and hepatitis B, but for AIDS infection as well.

Senator WEICKER. Do you have enough money in this budget to permit financing that type of investigation?

Dr. MASON. Yes; we do. There is $12 million in this budget for AIDS investigation.

Senator WEICKER. That certainly won't solve the problem, but it will certainly take care of one aspect of the situation.

Dr. MASON. If the agent is identified, this just begins the work. The application involves prevention of the disease through changes in lifestyle, but we also need to have a vaccine or some way to treat the disease so that it doesn't have this high fatality rate. If we have the agent, then that just begins the activities that have to be carried out to control the disease.

### TUBERCULOSIS

Senator WEICKER. I have further questions for response to the record. I would very much like to continue some of these myself, but I am afraid time does not permit because a vote is going on.

I will ask one more question before we submit the questions for response to the record, and that will be the end of your necessity to testify.

Once again the Department is requesting no categorical funding for tuberculosis grants for which the Congress appropriated $5 million in fiscal year 1984.

Is the incidence of TB among children on the rise in this country? Is the $5 million which Congress provided for TB grants being used effectively or, in your opinion, is it duplicative of other efforts and is not necessary?

Dr. MASON. Mr. Chairman, the number of tuberculosis cases in the United States declined by 7.8 percent, comparing 1982 with 1983. So the disease is on a decline. We have used the $5 million to target high risk areas. There are some States that have very little tuberculosis; there are some States and communities that have more tuberculosis; and so the $5 million has gone to target those areas through grants where there have been problems.

It is our position that the preventive services block grant and refugee money can be used and applied for tuberculosis control, giving the local areas that flexibility. That is why the $5 million is not in the budget.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Before I turn the chair over to Senator Eagleton the rest of the questions which I referred to earlier will be inserted in the record.

Senator EAGLETON [presiding]. I thank the folks from CDC.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### GENERAL STAFF LEVELS

Question: What is the specific rationale for proposing this reduction?

Answer: The reduction is part of the Administration's effort to reduce the size of the Federal civilian workforce.

Question: Which programs or areas would be affected by this reduction in staffing?

Answer: This reduction will be accomplished by attrition and by the utilization of administrative and program efficiencies and will affect most all programs of CDC except for AIDS research.

Question: Which "public health professional" in OMB made the decision to reduce the staff of the Centers for Disease Control, a critical agency responsible for protecting the health of all our citizens?

Answer: Decisions on agency staffing levels were negotiated between the Department and the Office of Management and Budget (OMB) and represent the government-wide effort to reduce overall Federal civilian employment. The staffing reductions can be accomplished primarily through attrition throughout the agency, by administrative efforts to improve agency efficiency in conjunction with the President's "Reform 88" initiatives, and, if necessary, by reducing non-permanent staff. These reductions are not expected to impair the agency's abilities in any measurable way.

### VD PROGRAM STAFF LEVELS

Question: States receiving various CDC grants may opt to receive a portion of their award in the form of positions in lieu of cash. In other words, many choose to receive assistance in the form of actual health professionals on loan to their health departments. Your justification states that there will be a decrease of 50 positions in lieu of cash available to the States in FY'85 for public health advisors in the venereal disease program. Are these the 50 positions that the Congress added last year?

Answer: Yes, they are the same fifty that Congress added.

Question: Did CDC actually ever receive the authority for these 50 positions from OMB in FY '84?

Answer: No, CDC did not receive FTE's for the 50 positions. However, our overall FTE level for VD grants would be 411 FTE's in 1983, 448 in 1984 and 1985.

Question: Since the States are paying for these positions out of their grant allotments, it won't cost any additional funds to fill the positions. For what reasons will these 50 positions not be made available? Who made the decision?

Answer: We believe that this request reflects an adequate level of human resources which meets the current demand from the States for these in-lieu-of-cash assignees since many programs have been streamlined and made more efficient. Sex partner referral efforts and routine screening of various population groups for asymptomatic gonorrhea and syphilis, in particular, have been increasingly targeted to high yield groups and are being accomplished with fewer human resources.

## VENEREAL DISEASE

Question: How has the venereal disease program within the Centers for Disease Control contributed to the prevention, treatment and control of sexually transmitted diseases?

Answer: In FY 1983, the Division of Sexually Transmitted Diseases of CDC provided technical and financial assistance to a total of 64 project areas, including all 50 States, the District of Columbia, 7 local areas, and 6 U.S. territories. Accomplishments include the following:

- Through gonorrhea screening and other outreach efforts, prevented an estimated 168,500 cases of uncomplicated disease and 26,500 cases of pelvic inflammatory disease (PID). Minimum savings from Federal assistance were estimated to be over $100,000,000 providing a ratio of benefits to costs of 3.0:1.

- Assisted grantees in maintaining intensive STD surveillance, as well as implementing outbreak investigations, for potential antimicrobial resistance, such as penicillinase-producing Neisseria gonorrhoeae (PPNG). These efforts reduced the number of reported cases to 3,900 cases in FY 1983, a 5.3 percent reduction over the number reported during the same period a year before. This decrease represents the first reduction since the introduction of the organism in 1976.

- Through outreach efforts in syphilis control, prevented an estimated 6,100 new infections in FY 1983.

- Continued support for 10 Model STD Prevention/Training Centers to improve STD diagnostic and treatment skills. A total of 1,721 physicians, nurse practitioners, nurse clinicians, and physician assistants were trained during the year. In addition, 589 disease control personnel were trained in disease intervention approaches.

- Assisted project grantees in establishing targeted screening programs for the identification of gonococcal infection in women resulting in 7.8 million culture specimens being obtained from women, 327,700 (4.2 percent) were found to be positive for gonorrhea, and 304,600 (93.1 percent) of these females were located and treated.

- Assisted project areas in maintaining gonorrhea sex partner referral activities. As a result, 197,700 individuals were examined as sex partners to gonorrhea cases. Of these sex partners, 154,500 received treatment or preventive treatment for gonorrhea.

- Assisted 60 project areas in establishing control efforts to identify, treat, and counsel women with gonococcal PID. Approximately 30,000 cases were identified, and 87 percent were counseled. Of all infected sex partners, 46 percent were asymptomatic.

- Assisted grantees in maintaining reactor followup programs for the identification of untreated cases of syphilis. Forty-five million serologic tests for syphilis were performed at the national level. A portion of these reactors were followed by project area personnel to identify individuals in need of diagnosis and treatment.

- Assisted grantees in maintaining syphilis sex partner referral activities resulting in: 104,200 suspects identified, referred, and examined; 12,100 new syphilis cases detected and treated; and 33,900 additional persons, exposed to syphilis, received preventive treatment.

- Continued collaborative efforts with State and local areas to install additional STD Management Information Systems.

- Distributed "Sexually Transmitted Disease Treatment Guidelines" (1982) as well as "Quality Assurance Guidelines for STD Clinics" (1982) on a national scale.

- Completed classroom curriculum materials (teacher and student handbook) for use in grades 9-12 under contract with Purdue Research Foundation. Materials accepted by national school-health text, published for national distribution.

- Conducted applied research efforts directed toward evaluating control strategies.

Question: What major problems do we still face in the control of sexually transmitted diseases? Why are you requesting no increase in the CDC budget for sexually transmitted disease activities in FY 1985?

Answer: Considering the ever-increasing spectrum of sexually transmitted diseases, a continuing need exists to upgrade the professional skills of clinicians in both the public as well as the private sector. Although the STD Prevention/Training Centers have provided practicing clinicians with an opportunity to refine their diagnostic and treatment skills, medical schools need to greatly improve the quantity and quality of the STD instruction they provide.

Control efforts for STD organisms other than syphilis and gonorrhea are hampered by the lack of further technological advancements. Herpes simplex virus (HSV) infections as yet have no effective cure. Chlamydial infections lack simple and inexpensive diagnostic techniques.

The relationship of STD to infertility and pregnancy outcome needs to be further defined.

We believe that the request for FY 1985 reflects an adequate level for STD control efforts. To improve the effectiveness of STD funds, many program activities have been streamlined and made more efficient. For example, sex partner referral efforts and routine screening of various population groups for asymptomatic gonorrhea and syphilis, in particular, have been increasingly targeted to high yield groups and are being accomplished with less human resources. This will allow us to meet basic needs in other STD areas, such as, continued support for chlamydial infection demonstration control efforts, as well as, professional education efforts in both chlamydial and herpes infections.

Question: A study published by the Journal of the American Medical Association determined that medical students today are woefully undertrained to deal with sexually transmitted diseases. Do you agree with this conclusion? What more could be done to ensure that future physicians are adequately trained in this area?

Answer: We do agree with the study. A large portion of medical schools offer no STD clinical training and the average number of didactic hours devoted to STD in the medical school curricula total was found, in the study mentioned above, totally unacceptable - totaling approximately 6 hours during the four year medical training program. This represents 0.1 percent of a student's typical curriculum.

There is a need to improve the quantity and quality of STD curricula in medical school training programs. In FY 1984, CDC will be funding approximately five or six medical schools under special 318(b) demonstration funds, to develop, implement, and evaluate STD curricula within the medical school instructional program.

## VACCINE STOCKPILING

Question: The Department is working toward the goal of maintaining a sufficient stockpile of vaccines. Your budget requests $4 million, the same as the previous year, to increase the duration of vaccine supply from 11 to 16 weeks, which amounts to 60% of your stated goal of a six-month supply. What are the reasons for the need for a six-month stockpile of vaccines?

Answer: If production of a vaccine were to be totally interrupted, the best estimate by the FDA is that it would likely take 6 months or more to re-establish production or to license a foreign manufacturer who is already in the business of producing vaccine. This timetable is based on requiring a period of: a minimal time of 1 month needed to grow cultures and manufacture vaccine; an average time needed of 4 months for manufacturer to conduct animal tests required by FDA to ensure vaccine potency and efficacy; and approximately 1 month needed for product labeling and distribution.

For complex vaccines (e.g. polio) or major production problems, FDA requires manufacturer to produce 5 consecutive lots of quality vaccine, and each lot must be tested.

Question: How much would be needed to achieve your goal of a six-month vaccine supply?

Answer: Completing the stockpile for OPV, MMR, and IPV vaccines in 1985 would cost between $10,743,240 and $11,813,560, depending on whether funds were available to purchase these vaccines before December 31, 1984 when the present contracts expire and after which the vaccine prices are expected to increase an additional 10 percent. It is not possible at this time to estimate accurately what it would cost to complete the stockpile for DTP and Td vaccines in 1985 because of recent significant price hikes for these vaccines. Today, States are paying over 98 cents per dose for DTP and Td vaccines compared at 37.5 cents for DTP and 11.8 cents for Td in June 1983. We should be receiving bids on our contracts for the purchase of DTP and Td vaccines around mid-May in which we expect to receive some discount for our bulk purchase.

Question: Why are you not requesting the full amount for a six-month vaccine stockpile in FY 1985?

Answer: Building the stockpile over a period of time avoids the need for a sudden large increase in production which might present problems for the manufacturers and result in increased costs. We also believe that current plans will provide a necessary cushion in the period during which the stockpile is being built. Spreading the cost over a number of years helps us in controlling federal spending.

## INFECTIOUS DISEASES - TUBERCULOSIS

Question: Once again, the Department is requesting no categorical funding for tuberculosis grants for which the Congress appropriated $5 million in FY 84. Specifically, besides this grant program, what funding is available both within CDC and the Department as a whole, to address the tuberculosis problem?

Answer: Based on 1982 reports from the Association of State and Territorial Health Officers, we estimate that in excess of $1 million in Preventive Health and Health Services Block Grant funds are spent for tuberculosis prevention and control services which are provided by tuberculosis, laboratory, nursing, and other communicable disease components of health departments.

In addition to the funds available through the block grants, refugee funds are provided to State and large metropolitan health departments for health assessment and referral services, including tuberculosis. These funds amounted to $3,894,000 in FY 1983 and $5,810,000 in FY 1984. In 1984 the refugee funds were increased to permit health departments to employ outreach workers to assure the treatment of refugees with tuberculosis infection. In FY 1985, the Administration is requesting additional funds to permit this increased support to health departments for activities related to tuberculosis among refugees.

Question: Is the incidence of TB among children on the rise in this country? What about the population overall?

Answer: The incidence of tuberculosis in children in the United States has been declining for many years. From 1962 through 1975, the tuberculosis case rate among children 0-14 years of age decreased from 10.4 to 3.7 cases per 100,000. The average annual rate of decrease was 8.8 percent. From 1976 through 1981, the rate changed from 3.4 to 3.3 cases per 100,000--an average annual decrease of only 0.6 percent. Available data suggest that Hispanic and Indochinese refugee children accounted for the relative stability of the case rates. In 1982, the most recent year for which tuberculosis data by age are available, 1,349 cases were reported in children 0-14 years of age; the case rate dropped to 2.7 per 100,000--a decline of 18.2 percent from 1981. Factors that may have contributed to the decreased number of tuberculosis cases in children in 1982 are a decline in the number of refugees arriving in the United States and a decline in the number of refugees arriving with tuberculosis.

The Centers for Disease Control (CDC) is reporting a provisional tuberculosis case total of 23,532 for 1983. During the years 1962 through 1978, the average annual decline in U.S. tuberculosis cases was 5.8 percent. From 1979 through 1981, the average annual decline was only 1.4 percent. The 25,520 cases reported in 1982 represent a 6.8 percent decrease from the 27,373 cases reported in 1981. The 1983 provisional total represents a decrease of 7.8 percent from 1982. The increase in the rates of decline in 1982 and 1983 are partly a result of a reduction in the number of new refugees arriving with tuberculosis and partly a result of more accurate verification of counted cases.

Question: Is the $5 million which Congress provided for TB grants being used effectively, or is this funding, in your opinion, merely duplicative of other efforts underway?

Answer: These funds are being used effectively and are not duplicative of other efforts. The 48 health departments receiving Tuberculosis funds are submitting narrative progress reports with information showing the intensified control activities, funded through this $5 million program, are having a major impact on tuberculosis. This is because funds are being used primarily to demonstrate the effectiveness of using outreach workers in the Nation's high-incidence areas. The outreach workers interact with patients who are unable or unwilling to self-administer therapy. The outreach workers motivate the patients and directly observe them taking prescribed medications. For instance, a number of health departments first funded in late 1982 are showing that high percentages of patients followed under this program have completed or are continuing treatment: Baltimore, 100 percent; Chicago, 90 percent; Philadelphia, 86 percent; San Francisco, 85 percent; Washington, D.C., 97 percent; and Puerto Rico, 71 percent. Some areas are also reporting substantial cost savings because noncompliant patients who previously needed to be hospitalized for relapse of tuberculosis can now be successfully treated on an outpatient basis. After 1-3 years of demonstrating the use of intensified outreach in high-incidence areas, the States will be in an excellent position to evaluate these activities and determine where they rank among their other priorities. The

Preventive Health and Health Services Block Grant funds may be used by the States to continue these activities, if the States wish to do so.

AIDS BLOOD SCREENING

Question: One of the many problems associated with AIDS is that it can be transmitted through blood transfusions involving AIDS-contaminated blood. Last October, a three-year old California boy died from AIDS which he apparently contracted by receiving a blood transfusion at birth, of which his parents had been completely unaware. CDC has been aware of blood transfusion related AIDS cases since July of 1982. How is donated blood screened for the possible existence of AIDS?

Answer: Since we do not know the cause of AIDS, a test to determine the presence or absence of AIDS in blood, blood components, or products is not yet developed. However, AIDS Prevention Recommendations of the Public Health Service, made in March 1983, were designed to limit blood donations by members of AIDS "risk groups." The recommendations say that, as a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at little risk of AIDS. Centers collecting plasma and/or blood should inform potential donors of this recommendation. The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives and for establishments collecting plasma and blood. This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available.

Question: What is the Department doing to establish a uniform blood screening policy for all licensed blood banks and hospitals?

Answer: Until the cause of AIDS is found, and a specific test for AIDS developed, a uniform blood screening policy cannot be developed. However, research is in progress and preventive measures are being taken to eliminate the risk of AIDS contamination to the nation's blood supply. There is wide spread dissemination of the Public Health Service Interagency Prevention Recommendations, which state that members of groups most at risk for AIDS stop donating blood. The FDA has approved a method to process Factor VIII (used in the care of persons with hemophilia) in a way that will reduce the risk of transmission of certain viruses, and perhaps AIDS. The FDA has also issued guidelines on AIDS prevention to be used in centers collecting blood and plasma in the United States.

The Food and Drug Administration; the National Heart, Lung, and Blood Institute (NHLBI); and CDC are coordinating research programs. At CDC, epidemiologic investigation of transfusion-associated AIDS cases and their donors is ongoing. In addition, investigative work is being carried out in cooperation with the National Hemophilia Foundation. At a February 14, 1984 meeting, representatives of State and local health departments, the American blood community, FDA, NHLBI, and CDC planned additional programs and research to address these issues.

Question: How much would it cost to develop and administer such a blood screening procedure?

Answer: The cost is unknown. The cause of AIDS needs to be found before a specific test to determine the presence or absence of AIDS can be developed. Currently, surrogate tests are under investigation. If AIDS is found to be caused by a virus, we might anticipate that testing of donated blood for evidence of active infection with this virus could be done relatively inexpensively.

## ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

Question: The Centers for Disease Control is an important partner in the fight against AIDS in this country. Is the number of new cases reported on the increase or on the decrease?

Answer: From June 1981 until April 9, 1984, the number of AIDS cases (4,023) and deaths (1,746) has continued to increase. Since July, 1983, an average of approximately 50 new cases each week has been reported.

Question: Is the mortality rate increasing or decreasing?

Answer: The overall mortality rate has continued to increase and is now approximately 43 percent. However, the mortality rate increases with increasing time from diagnosis. About 86 percent of persons with AIDS die within three years of its diagnosis. There is no evidence that these rates have changed.

Question: What do we know today about the causes and treatment of AIDS that we did not know three years ago when our nation first became aware of the seriousness of this condition?

Answer: The cause of AIDS is unknown. However, epidemiologic studies and laboratory evidence indicate that AIDS is caused by an infectious agent, probably a virus, that attacks the immune system. Although it is not possible to predict exactly when the cause of AIDS will be found, we anticipate that sufficient evidence will be accumulated over the next few months to strongly implicate one virus as the primary causative agent of AIDS. Retroviruses, such as those related to human T-cell leukemia virus (HTLV), appear to be promising leads. No scientific tool, laboratory process, or epidemiologic technique is being overlooked in the search for the cause of AIDS. However, epidemiologic findings have made it possible to establish effective steps to prevent AIDS, even though its cause remains uncertain.

There is no specific treatment for AIDS. Although certain treatments are being tested, we know of no documented evidence of an AIDS patient's compromised immune system being restored to normal. There are, however, effective therapeutic measures to treat the opportunistic infections that AIDS patients may suffer. Chemotherapy is available to treat the cancers seen in AIDS. Research of potential methods to treat the immune system of AIDS patients is a major activity of NIH investigators.

Question: You are requesting $12 million, the same as last year's level for CDC's AIDS efforts, including your cooperative program with the New York City Health Department. Do you feel that this $12 million is adequate to carry out all of the activities relating to the diagnosis, control and prevention of AIDS? Is there a chance that with this level of funding, you may need to divert funds from other CDC areas for AIDS activities in FY '85?

Answer: At this time, we believe the $12 million budget request is adequate, and we do not anticipate further staffing diversions. However, if a breakthrough occurs, the direction of our work may change and that may change our needs in terms of financial and personnel resources. The Assistant Secretary for Health has assured us that if there is a need for additional funds, that need will be pursued.

Question: As part of the President's overall effort to reduce the federal non-defense employment, will any positions currently assigned to AIDS activities be eliminated?

Answer: To date, no plans have been made to eliminate any positions currently assigned to AIDS activities.

Question: To what extent is the Department involved in public education targeted for AIDS "at risk" groups?

Answer: We have developed and implemented a PHS-wide plan for AIDS information and education for risk groups, health workers, and the general public which involves several PHS agencies and offices. The education program is organized around specific objectives and particular target populations. The activities of this plan include a national AIDS hotline; regular publication, and distribution of Facts About AIDS; development and distribution of videotapes for health workers and risk groups; and multi-lingual printed materials for risk groups. During April and May 1984, regional workshops will be sponsored by CDC to assist State and local health departments in planning and conducting community-based education/information programs. CDC is also funding a cooperative agreement with the U.S. Conference of Mayors to establish a national AIDS information interchange system among city governments. In addition, CDC continues to provide timely information in the Morbidity and Mortality Weekly Report on the results of epidemiologic and laboratory studies and surveillance activities.

USER FEES

Question: In the past, the Department has opposed user fees at CDC because the activities are intended solely to protect the health of the people in this nation. In looking at your biographical data, Dr. Mason, I note that you were the Director of the Utah State Department of Health as well as the former Director of Laboratories for the CDC.

Your budget (p. 282) states that "In FY 1985 CDC will charge a user fee...for reference diagnostic services provided to State health department laboratories, to clinical and public health laboratories throughout the nation." This would "save" an estimated $2 million in FY 1985. What type of diagnostic services do you provide to the States?

Answer: CDC provides reference/diagnostic testing to the States on the following: cultures, serum samples, tissues, or histologic specimens from patients suspected of having unusual infectious diseases; other kinds of clinical specimens that aid in the diagnosis of life-threatening, unusual, or exotic infectious diseases; cultures or serum specimens obtained from patients who have infectious diseases that occur only sporadically or who are involved in outbreaks of diseases caused by organisms for which reagents are not commercially or widely available; organisms that do not appear to be "usual" pathogens or are associated with hospital-acquired infections; and specimens that are clinically important and are forwarded to CDC for confirmation because earlier test results were difficult to interpret or require confirmation for quality assurance.

Question: In your professional opinion, Dr. Mason, what will be the effect of charging for these services? Is it likely that some States might not request CDC assistance in analyzing certain specimens or in other diagnostic areas due to lack of funds to pay for it?

Answer: Since we just recently notified the States of the fee, it is to early to know exactly what the States will do.

Question: Is it possible that a major disease outbreak could be missed or the medical response delayed as a result of the imposition of a fee to the States for diagnostic services?

Answer: While it may be possible, it is unlikely.

Question: Does the CDC have the statutory authority to charge user fees without the Congress including the enabling language you provided along with your budget submission?

Answer: The statutory authority to charge user fees is covered by the User Fee Statute; 31 USC 9701. However, CDC does need the enabling language requested in our budget submission to deposit the fees collected into the Disease Control appropriation, rather than the General Fund Account of the Treasury, so that the funds can be used to offset the requested reduction of $2 million in the epidemic services budget activity.

## HERPES

Question: We have heard a great deal in the last few years about herpes. Is the incidence of herpes as much of a problem today as it was two years ago? How many new cases of herpes are reported each year? How many Americans suffer from herpes?

Answer: Since herpes simplex virus (HSV) infection is not a reportable disease in the majority of States, reported morbidity trends are not available. However, visits to office-based physicians (based on the National Disease Therapeutic Index) for HSV infections indicate that the private physician office incidence of this disease may be rising. The number of consultations for these infections increased ten-fold between 1966 and 1981.

As indicated previously, HSV infections are not reportable in the majority of States; as a result, we have no information available on the annual numbers of new reported cases. We estimate that between 300,000-600,000 new HSV infections occur each year and between 5-20 million Americans are afflicted with recurrent HSV infections.

Question: What do we know about herpes that we did not know 5 years ago regarding the causes and treatment of herpes? How close are we to developing an effective treatment? What about a cure?

Answer: Recent research on herpes has further clarified its role as a sexually transmitted agent. For example, we now know that herpes simplex virus Type I, the agent primarily responsible for oral herpes, is also capable of causing genital herpes. Moreover, we have much more accurate information on the clinical manifestations, course, and complications of genital herpes infections. Although antiviral therapy is not curative, it may provide a basis for prophylaxis.

Emory University, in collaboration with CDC, is continuing an NIH-funded grant to study the epidemiology and natural history of HSV infections. Projects continue to focus on transmission of the organism, HSV infections in pregnancy, and seroepidemiologic studies.

While no curative therapy exists for either adult or neonatal disease, progress continues in the development of effective antiviral agents. One of the most promising agents, pending approval by the FDA, is oral acyclovir. Although this therapeutic agent appears to effectively suppress the virus and prevent recurrences, it needs to be evaluated for potential long-term toxicity and/or the development of viral resistance.

Question: How much do you expect to spend on herpes activities in FY 1985?

Answer: CDC plans to spend approximately $1.3 million on genital herpes infections in FY 1985.

Question: How many babies are born with herpes each year?

Answer: The number of cases of neonatal herpes simplex virus (HSV) infection occurring each year in the United States is unknown. Although estimates range from 100 to 1,200 annual cases, CDC estimates that approximately 400 cases occur each year. We have recently funded a national surveillance system for neonatal herpes which will help us better understand the extent and characteristics of this problem.

Question: Why is it that we do not have a nationwide surveillance program for herpes in this country?

Answer: At present, HSV infection is not a reportable disease in the vast majority of States. As a result, a national surveillance program for adult HSV infections is not possible. However, CDC initiated a pilot national neonatal herpes effort in FY 1983 to attempt to document, as accurately as possible, the number of cases occurring in the United States and to identify risk factors for the infection in infants and parents. Information is currently being collected on suspected or confirmed cases of newborn herpes simplex infection from participating State health departments as well as cooperating hospitals with major pediatric units. We expect that 50 to 60 percent of cases occurring during this 18-month period will be reported to CDC.

## OCCUPATIONAL SAFETY AND HEALTH

Question: As your budget indicates, the National Institute for Occupational Safety and Health (NIOSH) is the only federal organization with a specified mission to conduct health research in industrial populations. Statistics indicate that about one of every ten workers in private industry suffers an occupational injury each year; four out of 100 workers are disabled from these injuries and about 7 out of every 100,000 workers are killed on the job.

Your budget request amounts to more than a $9 million decrease from FY 1984, with most of that decrease coming from your proposed elimination of funding for the training of occupational safety and health professionals. We've seen this proposal before and rejected it. Aside from elimination of funding for training, what research activities would be eliminated or reduced?

Answer: The additional $1.5 million requested and appropriated in 1984 for research grants has been maintained into 1985. The Congressional add-on of $1.5 million for industry-wide studies would not be restored.

Much of the Institute's research is in the area of industry-wide studies. The increase of $1.5 million has supplemented our research in this area and allowed us to begin new studies this year. Generally these are long term studies averaging between 3-5 years in length and the increase in the FY 1984 budget will be for data collection and the resource intensive activities of these projects with an inhouse effort anticipated in future years.

Question: Have the number of Health Hazard Evaluations you are requested to conduct increased or decreased in the past few years? What percent of those requested are you able to complete?

Answer: In Fiscal Year 1981, NIOSH received 513 health hazard evaluation requests. In Fiscal Year 1982, this decreased to 423. However, for FY'83, this increased to 494 and for the first half of FY'84, we have received 276.

NIOSH responds to every health hazard evaluation received, but we do try to prioritize our response based on the severity of the problem, the availability of other sources of assistance (e.g., state health departments, state consultation programs, OSHA). A health hazard evaluation takes an average of 6 months from the initial request to its completion. Therefore, there is not a direct relationship between the number of requests received and the number of requests completed in a given fiscal year.

Question: How have the nature of occupational related injuries and deaths changed over the past decade?

Answer: Unfortunately, there is no adequate method of measuring changes in the nature of occupational related injuries and deaths over the past decade at the National level. At present, there is no systematic, routine reporting system for work-related diseases and injuries. The limitations of the existing data bases often preclude obtaining baseline data with which to follow incidence trends for specific diseases and injuries.

However, there are two data bases that have been created by NIOSH that may be used in the future to answer this question: the National Occupational Hazard Survey (NOHS) and the National Occupational Exposure Survey (NOES). NOHS was conducted from 1972 to 1974, while NOES was conducted from 1981 to 1983. These surveys collected information on potential occupational exposures and described the health and safety conditions in a representative sample of industrial facilities covered under the Occupational Safety and Health Act of 1970. Since 1974, there have been substantial changes in workplace hazards, in the mix of industries seen by the two surveys, and in the use of control technology. Data compiled from these surveys will form the basis for the analysis of industrial hazard exposure trends, the degree to which plants have implemented programs to reduce occupational health problems, and the extent of control technology and health-related services. This analysis is not expected to be completed until FY 1986.

Question: Can you cite some specific examples of the ways in which federal involvement in these areas has actually prevented illness and injury and actually saved lives?

Answer: Without a large, comprehensive surveillance system in place, it is difficult, if not impossible to estimate the number of lives lost or saved due to Federal programs. NIOSH has published: 110 criteria documents assembling international scientific information and recommending occupational safety and health standards; 39 current intelligence bulletins which alerted the occupational safety and health community to new hazards; 55 health and safety guides oriented to conveying hazard information and good practices to workers; and 471 other publications showing research findings and recommendations. The use of this information has prevented illness and injury and saved lives, and will continue to do so as the information is used to design and construct new plants and equipment and training and safety programs.

Another example of NIOSH program effectiveness is the health hazard evaluations of the pesticide dibromochloropropane (DBCP) when it was observed that groups of exposed male workers at 2 chemical companies had problems of infertility. These investigations started a process which led to EPA and OSHA severely restricting the wide use of DBCP.

The prevalence of vibration syndrome was found to be 19% among a population of shipyard workers and 47% among foundry workers. NIOSH has developed recommendations which has resulted in the redesign of hand tools to control vibration in the equipment used in these and other industries.

Question: Do you have any estimates of the health cost savings to the Government which have resulted from our investment in occupational safety and health research and training?

Answer: Health care cost savings from occupational safety and health programs are difficult to estimate because of the size of the work force, the variety and duration of jobs, and the difficulty in defining exact cause and effect relationships. The National Safety Council estimated that the total cost of occupational injuries alone is over 32 billion dollars annually, resulting from 2 million injuries and fatalities in the workplace. Two recently completed (unpublished) studies provide estimates of these economic costs:

> Logging injuries. The total annual cost of logging injuries in 1978 dollars on an assumed work force of 85.4 thousand is $79 million, including $70 million in lost productivity, which accounts for over 88% of the total. These costs come disproportionately from workers over forty years of age, in part because they have higher wages, but mostly because they suffer the most severe injuries which are likely to result in death or long-term disablement.
>
> The average cost of a single injury varies from $4.4 to $3.1 thousand, depending on the discount rate used (2.5% to 10.0%). Injuries occurring to persons in the 40-64 age group are by far the most expensive, almost double the average cost for all ages.
>
> Musculoskeletal and Connective Tissue Disease among Farmers. The largest contribution to costs incurred by excess musculoskeletal and connective tissue disease (MCTD) comes from long-term permanent disablements; major added expenses come from medical care costs due to MCTD.
>
> An estimated $8.6 million is spent on medical care costs for the proportion of farmers contracting MCTD in excess of non-farmers. An estimated $1.4 million in lost work time results for those who never became sufficiently disabled to meet the Social Security criteria for disability benefits. Those who do become eligible for SSA disability awards lose a present value of wages amounting to $24.8 million, for a total annual loss of $34.8 million.

The potential for prevention programs to save money is considerable.

Question: You indicate that you expect the Educational Resource Centers (ERC's) to become self-supporting. What indications do you have that the private sector will substitute for a lack of federal support in the training of professionals in occupational safety and health?

Answer: Some progress has been made in the area of private funding. The two California ERC's have supplementary state funding. The Washington ERC receives some funding via the state-wide workers compensation funding pool. Many of the ERC program institutions which are state-funded have increased hard money faculty support. Support from the private sector is minimal at this point, although several ERC's have begun discussions with potential non-Federal funding groups. One quasi-private sector funding mechanism is the American Industrial Hygiene Foundation which has developed a trust fund for scholarships and grants to individual students. These funds are partly corporate gifts and partly from individual donations from AIHA members.

This program was announced in 1976 as a pilot project to provide federal support as "seed money" to start new programs in occupational safety and health and accelerate existing ones at universities across the country. This program was in response to section 21 of the Occupational Safety and Health Act to provide an adequate supply of manpower in this field. The program has been a success.

In the original program announcement the Institute required that each ERC have an advisory council composed of representatives of private industry, community organizations, government, and others who would be users of the ERC as a regional resource in the area of occupational safety and health. Part of the charge and responsibility of this council was to look for alternate and additional sources of funding. We attempted to prepare the ERC's at the outset for the prospect of no federal funds past the initial five year period.

It is our belief that the support for the Educational Resource Centers should come from non-Federal sources who benefit directly from the employment of occupational safety and health professionals who have received academic or continuing education training from the Educational Resource Centers. Educational Resource Centers currently receive approximately 25 percent of their funding from sources other than NIOSH federal training grants (i.e., States, private organizations).

## PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Question: Once again we note that the Department is pressing on with its proposal to move the administration of the Preventable Health and Health Services Block Grant to the Office of the Assistant Secretary of Health from CDC -- a move we have annually rejected. What convincing and/or new arguments do you have that might cause us to reconsider our position to keep block grants within the HHS division where the professional expertise is?

Answer: We continue to believe that our proposal is reasonable. Consolidation of the administration of the block grants in a single agency will give States a single focal point for resolving any problems that arise in block grant management and will realize additional Federal efficiencies.

For the Preventive Health and Health Services Block Grant, the transitional period is complete and it is fully operational in the States. States have developed administrative systems for the operation of the block grant and now require minimal Federal assistance.

The consolidation will affect only the administrative functions related to reviewing grant applications, distributing funds according to formula, and reviewing State reports. Technical assistance required by the States would still be provided by CDC.

Question: Within the Block Grant authority $3 million is to be directed to activities aimed at Rape Prevention as well as the treatment of rape victims. What are some examples of the way in which the States are using Prevention and Service Funds? Is the funding provided by law sufficient to support the range of services by the States?

Answer: The funds provided under the block grant are used primarily to support 24-hour crisis intervention hotlines, psychological counseling, victim assistance and advocacy through all phases of medical care, legal investigation, possible prosecution, and consultation and education for professionals and the general public.

The $3 million provided under the block grant is the minimum amount that the States must spend for rape prevention. The States are allowed to spend more of the block grant allocation if they wish.

Question: What uniform monitoring, reporting, or compliance system is there to determine how and how well states are using their Block Grant funding? Is your information derived solely from pre- and post-expenditure reports submitted by the States?

Answer: There is no federally mandated reporting system under the block grant that requires the States to provide uniform information regarding program accomplishments.

The Association of State and Territorial Health Officers reporting system provides some information on what activities the States are supporting from the PH&HS Block Grant.

In addition, CDC compliance reviews (5 States reviewed in FY82 and 10 States each in FY83 and FY84) provide information that the compliance of the law is being adhered to by the States. Other sources, such as the Urban Institute Report and the annual audit reports, provide useful information on the use of funds.

## CHRONIC AND ENVIRONMENTAL TECHNICAL ASSISTANCE

Question: What is the nature of requests you are receiving for technical assistance from the States relating to natural or man-made hazards or to conditions having environmental causes in FY 1984?

Answer: During FY 1984, CDC has received request and provided technical assistance to State, local, and county health agencies, universities, national and international organizations, and other Federal agencies on a wide range of environmental health activities. This technical assistance is focused on laboratory epidemiologic efforts directed toward selected natural and other environmental hazards and on building State and local health agency capacity to address environmental related health problems. These efforts include: toxicity from lead, mercury, arsenic, and other heavy metals; health effects of exposure to organic chemicals such as dioxin (TCDD), polychlorinated biphenyls (PCB), polybrominated biphenyls (PBB), organochlorine pesticides, benzene, and cyclopentadiene type insecticide wastes; natural events such as tornados, heatwaves, extreme cold, volcanic eruptions, and floods; and indoor air pollution from asbestos and formaldehyde.

Question: Is the number of requests for CDC assistance in environmental hazards on the increase?

Answer: Yes, as the identification and awareness of environmental hazards has grown, the requests for CDC assistance has increased. For example in 1983 we received over 350 requests from Superfund related activity alone compared to 12 requests in 1982.

## ENVIRONMENT AND HUMAN BEHAVIOR

Question: Lately, the Committee has been receiving information from individuals and groups urging federal involvement in researching the effects of nutritional and environmental factors on human behavior? (i.e., foods, chemical contaminants, pollution, etc.) Has the Centers for Disease Control looked into the issue of the effects of environmental or nutritional factors on human behavior?

Answer: No, we have not studied directly the issue of the effects of environmental factors on human behavior. To the degree that childhood behavioral development is influenced by the mental status and general development of the child, we are examining this issue. Specifically, we have established surveillance systems over childhood development and disabilities including mental retardation which may be related to environmental toxins.

At the request of the Food and Drug Administration, CDC is assisting in the examination of reports concerning adverse reactions to the use of the artificial sweetner, Aspartame. These reactions have included some neurological and behavioral complaints. Since this study is in progress, no data are yet available.

Question: Do you believe there is any basis to the theory that human behavior (physical and mental health) can be affected by environmental factors?

Answer: We have no basis for dismissing the possibility that human behavior can be affected by environmental factors.

## INTERNATIONAL HEALTH

Question: What specific international health areas will CDC be involved with in FY 1985 and how much of your budget will be devoted to this effort?

Answer: In FY 1985, as in recent years, the types of international health areas in which CDC will be involved will include emergency epidemiologic assistance on request; applied research to discover ways to treat, prevent, or control diseases of interest to the United States; reference laboratory services and surveillance; implementing operational program(s) funded by agreement with U.S. Agency for International Development (AID); and training. Major priorities among these will be efforts to help develop effective primary health care programs (with the

World Health Organization and AID); collaboration with other countries to help them develop a national epidemiologic service which simultaneously trains national epidemiologists; and promotion of aggressive childhood immunization programs in other interested countries as a means of reducing importation of measles and polio especially into the U.S. Nearly $10 million is spent on programs through CDC of which slightly less than $2 million is HHS appropriated funds. The bulk of the remainder being AID funded activities followed by World Health Organization reimbursements.

Question: What is the relationship between the World Health Organization (WHO) and CDC in international health disease prevention and control?

Answer: CDC collaborates with the World Health Organization in much of our international health work. Some 29 laboratories at CDC have been designated as WHO Collaborating Centers, which gives us access to specimens from around the world (influenza, for example). Medical officers on loan from CDC direct two of WHO's most important programs, namely, the Expanded Program on Immunization and the Diarrheal Disease Control Program. Some of our research and training regarding international health problems is undertaken with, and sometimes partly funded by WHO. We also respond to international epidemics or emergencies at the request of WHO and the country concerned. The international interests of the two institutions are by no means identical, but do coincide quite often.

## IMMUNIZATION GRANT SUPPORT

Question: Since 1963, CDC has provided project grant support to assist State and local health agencies in planning, developing, and conducting childhood immunization programs. What percentage of school-aged children at present are immunized against the vaccine-preventable disease of childhood (polio, rubella, measles, pertussis, etc.)?

Answer: Immunization data indicate record high immunization levels for the children entering school for the school year 1982-83. These immunization levels were: 97 percent for measles, polio, and rubella; and 96 percent for mumps, diphtheria, pertussis, and tetanus.

Question: How do these figures compare with your overall objectives for the year 1990?

Answer: The objective for 1990 is to have at least 95 percent of children attending licensed day care facilities, and kindergarten through 12 grade fully immunized. As stated above, immunization data indicate immunization levels for the children entering school for the school year 1982-1983 have exceeded those objectives. These immunization levels were: 97 percent for measles, polio, and rubella; 96 percent for mumps, diphtheria, pertussis, and tetanus.

Question: Are there other childhood diseases for which the possibility of elimination is feasible in the immediate future? Is this possible given your current budget request for immunization?

Answer: We believe that indigenous transmission of many of vaccine-preventable diseases of childhood can be eliminated such that cases would only occur as a result of importation from some other country. That is our goal for measles and we consider it likely to be achieved by 1985. We feel that rubella elimination can be achieved, and that is included in our budget request for 1985. Mumps will disappear from the United States over the course of the next several years if we merely continue what we are doing now. We do not consider it cost-effective to try to accelerate that process. For all practical purposes, polio and diphtheria have already been eliminated from this country. Elimination of pertussis must await development of an improved vaccine and further knowledge of the exact epidemiology of the disease under current conditions. Work is proceeding in both areas. Because of the ubiquity of the casual organism, tetanus will only be eliminated when everyone has received tetanus toxoid. This also will happen over the course of the next several years. The average age of the patient with tetanus in this country is now over 60, and is rising every year.

## VD INFORMATION, EDUCATION, DEMONSTRATION, AND RESEARCH

Question: The authorizing legislation for the STD program requires that five percent of all appropriated funds be allocated to projects of information, education, demonstration and research. What projects have been supported under Section 318(b) of the authorizing legislation?

Answer: The announcement for special funds, available in FY 1984 under Section 318(b) of the Public Health Service Act, was published in the Federal Register on January 3, 1984, and the deadline for these applications was March 1. A total of 79 applications were received and these were evaluated by a technical review panel three weeks later. Funding decisions are currently being made on approved applications for research, chlamydial infection control demonstrations, medical school curricula demonstrations, and public information and education projects.

A total of 15 to 20 applications covering these four areas will be funded in FY 1984. In addition, project grants awarded to State and local health departments support a wide range of public information and education activities.

Question: Do you believe this has satisfied the intent of Congress in addressing the needs to educate the public about sexually transmitted diseases?

Answer: Yes we do. Approximately four to five of the special 318(b) applications, representing a total of $500,000, will be funded to support public information and education. Areas funded will include: Continuation of the STD National Hotline, providing information and referral services to over 65,000 callers a year; the development of a herpes audiovisual information system for herpes patients as well as high-risk community groups; and the development and evaluation of STD materials for use in health curriculum settings of high schools throughout the nation. In addition, all control program project grants include a wide range of public information and education activities.

## VIROLOGY LABORATORY

Question: In the FY 1983 Emergency Jobs Bill, the Congress appropriated $15,560,000 for the construction of a new virology laboratory. The Congress allowed the funds to be carried over into 1985. What is the status of the Virology Laboratory construction?

Answer: The design is now in progress. Concepts have been approved and schematic drawings are due June 27.

Question: Will construction be underway soon? Will the funds be obligated in FY 1985?

Answer: Construction is scheduled to begin at the earliest on February 14, 1985, and the latest, August 13, 1985.

Funds are scheduled to be obligated in FY 1985.

Question: Since the funds were provided in FY 1983, and won't be spent until FY 1985, have costs increased where the cost now exceeds the amount appropriated?

Answer: Construction costs have increased relatively little in the past year and are not expected to increase greatly during the next 12 months. At this time, it is felt that the appropriated funds are adequate.

## FORMER CATEGORICAL PROGRAMS

Question: What specific formerly categorical programs now included in the Block Grant appear to be receiving reductions in funding by the States?

Answer: Our reporting requirements do not include the detailed fiscal information necessary to provide the information requested.

The Urban Institute Report mentioned earlier indicates that the urban programs, such as rodent control and fluoridation, are not receiving the priority for funding that the State-wide programs receive, such as hypertension, health education, and emergency medical services.

## PERSONAL VIOLENCE

Question: An alarming fact reported in the press recently is the increase of suicides in this country, particularly among teenagers. If I am correct, there has also been a substantial increase in the number of homicides reported over the last two decades. Your budget documents indicate that CDC is looking into these serious problems. Specifically, what studies are planned or underway in the area of personal violence?

Answer: The committee is correct in observing that there has been a dramatic increase in the teenage suicide rate in this country. Since the mid-1950's, the suicide rate among people 15-24 has more than tripled. The most dramatic rates are found among young persons 20-24 with a rate twice that found for teenagers 15-19. Although the homicide rate has recently begun to decrease--the homicide rate among young black men, the group with the highest risk of death from homicide, decreased more than 25% from 1970 to 1978--homicide continues to be the leading cause of death in this group and homicide rates, in general, are still alarmingly high in the United States.

In the area of personal violence, CDC is conducting important studies in the area of: suicide--where it is looking at the suicide rates and risk factors among young persons, and among minority groups, and is trying to evaluate the effectiveness of suicide prevention centers in actually preventing suicide and suicide attempts; domestic violence--where CDC is undertaking a collaborative program with the Department of Public Safety, health and social service agencies, and the courts in the city of Atlanta in an ambitious attempt to study and intervene in the deadly cycle of domestic violence; homicide--where CDC is working with the Martin Luther King, Jr., Center for Nonviolent Social Change, the National Institute of Mental Health, and the National Institute of Justice in trying to coordinate a close look at the risk factors for homicides among young persons in this country.

Question: What do we know about the causes of the increasing personal violence in this country?

Answer: Although there are many speculations about the causes of the increase in personal violence in this country, there is little hard data to substantiate the causal contribution of any of these factors. Epidemiologic expertise is being applied at CDC to a number of studies to identify risk factors for both victimization and perpetration of personal violence in this country. We believe that some of these risk factors will include drug and alcohol abuse, socioeconomic and other stresses, mental illness, and family disintegration, but the important work remains to be done in confirming these hypothetical risk factors in a scientific fashion.

Question: What type of prevention and outreach programs could CDC support in these areas?

Answer: CDC first needs to collect and evaluate baseline information on the risk factors for interpersonal violence before designing prevention and outreach programs based upon this information. Depending on what is learned from the first step, such prevention and outreach programs might be designed for school-based educational programs and for multi-agency collaborative intervention programs, such as the domestic crisis intervention program in Atlanta.

Question: Is your budget request sufficient to address the whole area of personal violence, its causes and prevention?

Answer: While resources adequate to initiate these types of activities have been presented in the present budget, we believe that this is just the first step in a cycle which will lead to ultimate intervention and prevention of interpersonal violence.

Additional funds may be necessary when it comes time to devise, test, and implement actual programs based upon the research and information we are currently collecting.

Question: Are you working with other agencies both within HHS and in other Departments to address this serious matter?

Answer: CDC is sharing its expertise and interest in epidemiology and public health methodologies with other agencies both within HHS and other departments of the Government. CDC is collaborating closely with the National Institute of Mental Health, the Office of Human Development Services, and is working closely with the National Institute of Justice in trying to identify and study risk factors. In Atlanta, CDC is initiating a multiagency collaborative approach which involves social service agencies, the Department of Public Safety, the courts, and a variety of health and mental health delivery organizations.

## DIABETES CONTROL PROGRAM

Question: Are you personally familiar with the Diabetes Control Program?

Answer: I received an extensive briefing on the Diabetes Control Program shortly after becoming the Director of CDC. Before that I was State Health Officer in Utah, which is one of the 20 diabetes project States. I have had the opportunity to view the accomplishments of the diabetes control program from both perspectives.

Question: Is this program in some ways a model in the establishment of programs to improve the management of chronic care?

Answer: For several years, the diabetes control program has been recognized as a potential model for other chronic diseases. Diabetes is a major contributing factor for heart disease, blindness, renal failure, and amputations. The Diabetes Control Program has been seen as a model because diabetes shares risk factors (overweight, smoking, hypertension) and population characteristics (racial groups, elderly) with other chronic diseases. Similar control strategies, particularly patient and professional education, team care, and involvement of third party payers, are used in control of diabetes, hypertension, and certain other chronic diseases.

Many States' diabetes programs are administratively combined with hypertension and other chronic disease programs including cancer, arthritis, and kidney disease. Increasing programmatic relationships between diabetes and other chronic diseases also permits more efficient use of resources. The methods outlined in the "Diabetes Program Handbook" for developing and implementing diabetes control efforts are also applicable to hypertension and related chronic disease control programs.

A working relationship has already been established in many project States between diabetes and other public health programs serving persons with diabetes. For example, the Michigan diabetes control program and the State's hypertension program jointly developed an education module, "Hypertension in the Diabetic Patient", to be used in the State hypertension professional education program. The Pennsylvania diabetes program has developed a self-study kit on the prevention of adverse outcomes of diabetes in pregnancy. This module is a useful tool for maternal and child health programs and professional education activities. Both modules also serve as prototypes for addressing other complications of diabetes by improving provider knowledge.

In summary, there are many similarities between diabetes and other chronic diseases in terms of target populations, risk factors, programmatic functions, and opportunities for pooling of resources.

Question: What is the purpose of the Program and how has it demonstrated effectiveness in dealing with diabetes?

Answer: The overall goal of the CDC diabetes control program is to reduce excess morbidity, mortality, and cost burdens from the preventable complications of diabetes by translating effective control methods into community practice. The program is currently conducting more than 60 interventions and special studies in partnership with 20 States. A number of significant outcomes and positive results have already emerged from these activities, including:

- Reductions in hospitalizations among diabetics receiving outpatient education in ME, RI, KY, and MI.

- Distribution of 100,000 copies of "A Guide for Primary Care Practitioners" which is designed to provide health practitioners with state-of-the-art information and recommendations for preventing or reducing five major complications associated with diabetes. Intensive efforts are underway in the 20 States and elsewhere to translate the Guide into improved diabetes care and outcomes through continuing medical education programs. A patient version of the Guide is also near completion.

- Development of "CDC-State Patient and Professional Education Guidelines," which provide standards for the development and evaluation of diabetes education programs. These Guidelines are the cornerstone of a nationwide effort to establish a network of cost effective, quality patient education programs.

- Development of a "Diabetes Program Handbook" designed for individuals responsible for managing diabetes control programs. Based on information and experiences in the 20 States, the Handbook is being successfully used to plan and organize diabetes control efforts in several non-project States and foreign countries.

- Health insurance coverage for patient education and other essential services has been obtained in several States based on studies piloted by CDC which documented the cost effectiveness of these services.

In summary, the CDC diabetes control program has progressed from a series of discrete, time-limited interventions and studies in well-defined populations to potentially broad applications of demonstration findings and research advances in large geographic areas. In the course of accomplishing this, CDC has established a viable network for effectively applying information, tools, and strategies for preventing or ameliorating the costly complications of diabetes.

Question: What data do you have from existing programs relating to the effectiveness of the program?

Answer: Presently CDC, in partnership with 20 States, is conducting a wide range of interventions and special studies aimed at reducing morbidity and mortality from the complications associated with diabetes. Significant positive outcomes have resulted. For example:

1. Reduction of Hospitalizations Through Diabetes Patient Education

   Persons with diabetes are expected to assume a major share of responsibility for their own care. Evidence is growing that inadequate patient knowledge results in multiple hospital admissions, excessive use of emergency rooms, a higher incidence of both acute and chronic complications, and a resulting increase in the economic and social burden of this disease.

   Many project States have developed special interventions to assess the impact of carefully designed diabetes patient education programs. It is difficult to isolate patient education as a sole contributing factor, as changes in the health care delivery system and professional education frequently occur simultaneously. In three of the States which have reported to date, interventions have resulted in reductions in the number of hospitalizations and their associated costs. The savings are significantly greater than the costs of the interventions.

   The final report on the "Reimbursement Pilot Study for the Maine Ambulatory Diabetic Education and Followup Program," submitted to Maine Blue Cross and Blue Shield in November 1983, showed almost a one-third decrease in the number of hospital days is possible. This represents a net savings of almost $300 per patient over the cost of the education program. Based on these findings, the Board of Directors of Maine Blue Cross and Blue Shield made reimbursement for diabetes outpatient education a permanent benefit for their members. Similar coverage has been provided in Maine by Medicare, Medicaid, and a private insurance company.

   The Michigan Diabetes Control Program, in cooperation with the Saginaw County Health Department, established a program of home visits to help recently hospitalized diabetic patients with the management of their disease. Preliminary analysis of results from the 73 participants indicates a reduction in the total number of hospital admissions of 43%, and a reduction in the average length of stay from 9.4 to 8.7 days. Hospital admissions also decreased when diabetes was the primary diagnosis.

In Rhode Island, outpatient education classes were conducted for 193 persons with insulin-dependent diabetes mellitus. The program emphasized improvement of diabetes self-management. Health care utilization comparisons at 12-month pre/post course indicate a 58 percent reduction in hospital admissions for preventable complications of diabetes (defined in the study as DKA, hypo/hyper-glycemia, and infection). In this sample total persons requiring hospitalization decreased by 48 percent and days of hospitalization decreased 41 percent.

2. Progress in Third-Party Reimbursement for Necessary Diabetes Services

In addition to Maine, other States have reported that reimbursement agreements for essential diabetes-related services have either been reached or are being seriously considered by Blue Cross and Blue Shield, Medicare, Medicaid, and other agencies. Progress in this area reflects a growing awareness and acceptance of the results reported by the national diabetes control program and the project States.

Michigan's Task Force on Third-Party Reimbursement has been successful in obtaining statewide Medicare reimbursement for diabetes education in hospital outpatient settings.

Reimbursement for diabetes outpatient education demonstration programs has been authorized by Medicare, Blue Cross and Blue Shield, and/or other third-party practitioners with state-of-the-art information and recommendations for preventing or reducing complications associated with diabetes.

Many of the results of the 67 interventions and special studies currently underway should be applicable to larger populations and should ultimately result in improved care for a large number of diabetic patients.

Question: Isn't diabetes one of the most prevalent of diagnoses related to Medicare hospital admissions and don't we save much more than we spend in the Diabetes Control Program?

Answer: Yes, diabetes is one of the most prevalent diagnoses related to Medicare hospital admissions. In fact, only coronary arteriosclerosis is more common as a single diagnostic code among hospital discharges for persons over the age of 65, 95 percent of which are covered under Medicare. Overall, in 1980 there were 1,128,000 discharges with diabetes as a listed diagnosis in persons over the age of 65 representing 12 million hospital days. This represents nearly 12 percent of all discharges in this age group.

Results from the Maine Diabetes Project indicate that individuals participating in diabetes control education programs experienced one-third fewer hospitalizations after participation than before. They calculated that for every dollar spent in the education programs, $2.10 was saved in the first year alone.

## DIABETES FUNDING

Question: At what levels have the existing 20 State Programs been funded over the last three years and have they been funded at the level of the original commitment?

Answer: Over the last three fiscal years (FY 82-84), CDC has awarded the 20 State diabetes control programs about $3.7 million a year, an average of about $185,000 per program. Funding awards to the projects have varied each year. Each project has experienced both increases and decreases in annual funding, depending on a number of factors, including the total funds available and the number of projects funded in each year; when the projects were begun and the relative progress each has demonstrated; and the time period of the funding award cycle for each State in a given year. As examples, in 1977, the first year of the diabetes control demonstrations, 11 projects were awarded a total of $1.38 million, or an average of about $126,000 per project. However, in 1984, 20 State projects were awarded a total of about $3.6 million, or an average of about $182,000 per program.

Question: Do you think there is a need to expand these programs to other States? All 50?

Answer: The diabetes control program is currently conducting more than 60 interventions and special studies in partnership with 20 States. While a number of significant outcomes and positive results have already emerged from project experiences, CDC is not seeking additional resources at this time to expand the program to other States. More specifically, an adequate mixture of demonstration sites already exists, and non-project States seeking to establish diabetes control programs can do so using Block Grant funds and the tools developed in the 20 project States. Florida and Texas are examples of non-project States successfully applying information and tools developed in the project States.

Plans are underway to disseminate the findings of the interventions and special studies to all 50 States.

Question: What would be the cost of funding existing programs to the originally authorized levels of about $230,000?

Answer: CDC currently provides diabetes control program funds to a total of 20 States. Funding the existing programs at an average of $230,000 would cost approximately $4.6 million. About $3.7 million is now available for this purpose, or an average of $185,000 per State.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### NUTRITION SURVEILLANCE

Question: Dr. Mason, I understand that CDC has a nutrition surveillance program which is limited to some very specific areas such as detecting iron anemia, growth retardation and obesity in children as well as identifying problems with nutrition during pregnancy. Can you tell us what new problems were uncovered in these areas last year and whether this information might be applicable to related programs such as the Maternal and Child Health Block Grant or the Department of Agriculture's Nutrition Education Programs.

Answer: Over the last decade, the CDC Division of Nutrition has developed a system to monitor prevalences and trends of simple measures of nutritional status among high-risk pediatric populations attending publicly supported health and nutrition programs. Presently, on a voluntary basis, more than 30 States participate in the nutrition surveillance system. The results of this surveillance activity have consistently indicated over the years that there is a higher prevalence of nutritional abnormalities among these high-risk children than is expected in the general population. However, there has been no indication of a deterioration in nutritional status among the children during the period that surveillance has been underway, including the last year. The data suggests a modest improvement in iron anemia, growth retardation, and overweight.

The surveillance system is designed to monitor known measures of poor nutrition rather than to define new problems in a broad range of nutrition-related health areas. In order for the system to be practical, it must limit itself to the kinds of simple height, weight, and hematologic data which are available routinely and continuously from the public health clinics which provide surveillance data to CDC. The surveillance system could suggest the existence of new problems if there were a major change in the prevalence of abnormalities which are defined by these measures, including major changes in growth retardation, obesity, or anemia.

In regard to the applicability of the data to programs such as the Maternal and Child Health Block Grant or the Department of Agriculture's Nutrition Education Programs, data are available for and used by the State and local recipients of these federal programs. At the State and local level this surveillance system is used in defining the prevalence and location of nutrition-related problems, appropriate public health planning can be undertaken and so that nutrition education programs can receive guidance as to priority issues in nutrition-related illness.

Question: Why is this surveillance program limited to only a few areas? For example, how can you be sure that the recent developmental problems mentioned in the justifications concerning young girls in Puerto Rico does not have a nutritional component?

Answer: The CDC Pediatric Nutritional Status Surveillance System has been designed to collect data which can assess growth retardation, obesity, and anemia because these are among the most prevalent nutrition-related problems occurring in U.S. children. Moreover, the data with which these problems can be assessed are readily available in a continuous fashion from the public health programs which provide remedial services to these children. More detailed nutrition data, which addresses a wider variety of nutrition-related conditions, can only be collected in the context of a survey or epidemiologic investigation which is designed for that purpose.

Specific issues, such as developmental problems (e.g., premature telarche) among young girls in Puerto Rico, may be so complex in their origins that no regular survey or surveillance activity can contribute significantly to their solution. Premature telarche has been presumed to be hormonal in origin and is hypothesized to be due to environmental causes (i.e., exogenous hormones) to which mothers and/or infants were exposed through diet or other means. Although there is no basis for considering nutrition per se to be the cause, special studies would be required to investigate an unusual occurrence such as this.

## RUBELLA IMMUNIZATION

Question: Dr. Mason, The budget request includes $2 million to help eradicate rubella and congenital rubella syndrome from the United States. Given the fact that an estimated 0.7 million school girls are still in need of immunization because, as the justifications point out, some States either impose no such requirement on its young female population or else fail to enforce existing law, how do you plan to reach these potential victims?

Answer: A variety of efforts will be used to try to reach these young women. First and most important, we will encourage those States who do not require rubella immunization for all school attendance, or do not adequately enforce requirements for rubella immunization for post-pubertal females to either amend their present requirements or enforce their present requirements. The young women who have already left high school and are susceptible to rubella will be the most difficult to reach. Assuring high immunity levels in this group will require efforts directed to immunization: requirement in colleges; in family planning clinics; post-partum and post-abortion patients; by family practice and gynecological physicians; and of health care workers.

These activities will be enhanced by the development of public and professional educational-motivational material encouraging rubella immunization for these susceptibles.

Question: For the record, please let us have a list of the States mentioned in the justifications.

Answer: Alaska, Colorado, Hawaii, Iowa, Idaho, Louisiana, Maryland, Michigan, New Hampshire, New Mexico, Puerto Rico, Texas, West Virginia, Wisconsin, Wyoming all require rubella vaccinations in their laws, but do not require all student in all grades to have completed the vaccinations. For instance, in Idaho only students through grade 5 are covered while in Texas coverage is from kindergarteners through age 11.

In addition, in 12 other States where immunization requirements apply to all grade levels, there may be selective exemptions for post-pubertal females. These States are: Colorado, Illinois, Maine, Minnesota, Mississippi, Montana, New York, Ohio, Oklahoma, South Carolina, Tennessee, and Washington.

## NUTRITION EPIDEMIOLOGIC SURVEYS

Question: Can you tell us what epidemiologic surveys in nutrition were conducted last year and how States were able to use this information?

Answer: The CDC has assisted in a variety of epidemiologic surveys related to nutrition in the previous year including: field surveys of Pediatric anemias in rural Tennessee; surveys of nutritional status among Southeast Asian infants, children in Seattle, Washington and children attending publicly supported clinics in Massachusetts; data analysis assistance for a survey of nutritional status of children in welfare hotels in New York City; investigation of the nutritional status of low income children in St. Paul, Minnesota; and analysis of nutritional status data collected from children admitted to the Emergency Room of Cook County Hospital in Chicago.

These activities were in addition to the ongoing technical assistance which CDC routinely provides to States participating in the Pediatric and Pregnancy Nutritional Status Surveillance Systems. The States or local health departments who were assisted in these investigations used the data to examine the prevalence of abnormalities in specific subpopulations of particular concern; set priorities for the orientation of health programs; and define the need for additional nutrition-related activities to address specific problems.

CDC also assisted States in the collection of height and weight data among adults utilizing a telephone survey methodology. These surveys, combined with others completed in previous years with CDC assistance, have provided an aggregated data set which can address the prevalence of obesity or underweight among a sample of adults and which can relate obesity and underweight to other behavioral characteristics such as alcohol, smoking, exercise, and hypertension. These data have been used by individual States to assess the needs for health education and other activities directed towards chronic diseases in their adult populations.

Question: What nutritional surveys are planned this year and in Fiscal Year 1985?

Answer: A survey in Tennessee is currently underway to define the nutritional status of children consuming a vegetarian diet in a rural farm community. Continuing activities are also planned which will assist States to define specific nutrition-related problems among their own populations of special interest including, for example, Native American and Hispanic children in Arizona.

## NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Question: Dr. Mason, during last year's hearings your predecessor expressed concern over the scientific credibility of the work conducted in the past by the National Institute for Occupational Safety and Health. Apparently, several of the Institute's scientific recommendations had been called into question and had to be evaluated by outside groups. Can you tell us very briefly what these issues were and how they were resolved? (If the answer is no): let us have it for the record.

Answer: As Dr. Foege mentioned, the scientific credibility of the Institute's research had been called into question in the past. To ensure the scientific credibility of the Institute, Dr. Millar has taken steps to open up the deliberative process on NIOSH research projects. He has established an extensive peer review system for all NIOSH research projects. A Board of Scientific Counselors has been established to review the Institute's research program and individual projects. This board is composed of 10 leading scientists from across the country in a variety of disciplines.

## BIRTH DEFECTS SURVEILLANCE

Question: Dr. Mason, based on your statement, CDC's studies and surveillance of birth defects has uncovered a strong relationship between the use of the anticonvulsant drug valproic acid during pregnancy and the occurrence of spina bifida. To what extent does CDC share such information with the National Institutes of Health in view of ongoing research into this disease?

Answer: CDC has a completely open working relationship with the National Institute of Health (NIH) and specifically its component institute, the National Institute for Child Health and Human Development (NICHD). We share, through direct and informal personal contacts with NIH staff members and through published articles in the MMWR, our knowledge of the causes of birth defects gleaned from surveillance and epidemiologic activities. As a further example of this working relationship, NICHD participated in the development of and provided the initial funding to establish CDC's Birth Defects Monitoring Program (BDMP).

Question: What about the Food and Drug Administration which regulates the pharmaceutical industry? Do you disseminate data such as this for FDA's attention?

Answer: Yes, as an example, in September 1982, a CDC staff member learned about the suspicion that valproic acid might be associated with birth defects while attending the Annual Meeting of the International Clearinghouse for Birth Defects Monitoring Systems. Immediately upon his return, CDC fully informed FDA of the findings of the French investigators and of the studies planned by the clearinghouse. When some of these planned studies were completed in October, the findings were immediately communicated to FDA by telephone. In addition, CDC Staff members traveled to FDA and presented a comprehensive review of these study findings. As a result of these consultations, CDC and FDA coauthored an MMWR article on valproic acid and the manufacturer sent a warning letter to all American physicians.

Further, in the summer of 1983, FDA reported to CDC their and the manufacturer's suspicions that Accutane was causing severe birth defects. CDC, working with FDA and the manufacturer, gathered sufficient clinical information to conclude that Accutane is a human teratogen. CDC and FDA published these findings in a coauthored, April 1984, MMWR article.

Question: On page 282 of your justifications you discuss your plans to raise $2 million in user fees for diagnostic services provided to state health department laboratories. Frankly I don't see why you concentrate these fees on the states, which are, after all, simply carrying out their duty to provide a safe and sanitary environment for their citizens, when, according to a General Accounting Office report, you could raise $3.3 million "for the cost of testing services provided to private health care providers and clinical laboratories." Why don't you charge the private sector user fees and leave the states alone?

Answer: CDC does not provide reference diagnostic services directly to individual patients, physicians, or laboratories. At the request of States, CDC provides reference/diagnostic testing on the following: cultures, serum samples, tissues, or histologic specimens from patients suspected of having unusual infectious diseases; other kinds of clinical specimens that aid in the diagnosis of life-threatening, unusual, or exotic infectious diseases; cultures or serum specimens obtained from patients who have infectious diseases that occur only sporadically or who are involved in outbreak of diseases caused by organisms for which reagents are not commercially or widely available; organisms that do not appear to be "usual" pathogens or are associated with hospital-acquired infections; and specimens that are clinically important and are forwarded to CDC for confirmation because earlier test results were difficult to interpret or require confirmation for quality assurance.

Since we provide the service to the States, we would have to charge the States.

## VIDEO DISPLAY TERMINALS

Question: Dr. Mason, the National Association of Working Women recently testified before the House Subcommittee on Health and Safety concerning video display terminals which may be causing abnormally high rates of pregnancy problems. For example, it was reported that female VDT operators employed by United Airlines in its San Francisco office recently experienced an unusually high rate of miscarriages, stillbirths and birth defects. Do you plan to investigate this?

Answer: Yes, we have received a request for a health hazard evaluation from the employees at United Airlines. NIOSH investigators conducted an initial site visit to the facility in March and plan a return visit in late April.

To answer your question in general, to our knowledge, there have been no scientific studies which were designed to address the question of adverse reproductive effects and occupational VDT use. There has been data in a variety of media of 8-10 clusters of adverse pregnancy outcomes among VDT users. In each cluster, a small group of women experienced a number of adverse pregnancy outcomes. In some cases, the number of adverse outcomes were in excess of what would have been expected as a function of the background rates of these events. Such clusters may reflect a relationship between VDT use and adverse pregnancy outcomes, or may represent a chance occurrence which is statistically predictable. It is partially because of these recurring reports of clusters of adverse pregnancy outcomes that NIOSH has plans to do a reproductive health study on the effects of VDT use.

## SEXUALLY TRANSMITTED DISEASES

Question: Dr. Mason, the justifications indicate that although other sexually transmitted diseases are emerging as potentially serious health problems, the control of gonorrhea and syphilis will continue to be the Centers' major focus next year for control efforts. Wouldn't it make more sense to also address these similar diseases now on a national level rather than wait until they developed into more serious Federal concerns?

Answer: Not at the present time, since control efforts in other sexually transmitted diseases require further technological advancements before control programs can be initiated. Chlamydial infections, for example, lack simple and inexpensive diagnostic techniques. As a result, any control efforts at present would be far too costly for consideration on a national scale. The 1984 chlamydial activities are: a cooperative agreement with the Institute for Health Policy Studies, University of California, to develop, study and evaluate cost-effective analytical models for defining chlamydial control strategies; chlamydial control demonstration efforts are supported with grants; and basic laboratory and clinical research is being conducted to evaluate alternatives to expensive cell culture techniques.

Herpes simplex virus (HSV) infection, at present, has no effective cure. As a result, control programs in this area have severe limitations. Plans are underway to evaluate oral acyclovir, a promising therapeutic agent for HSV infection. This extramural research effort will attempt to determine the long-term toxicity and/or viral resistance levels associated with this therapeutic agent, and CDC has implemented a pilot national neonatal herpes surveillance project to better define the problem of neonatal herpes infection in the United States.

STD problems, other than gonorrhea or syphilis, are being addressed by the: STD National Hotline, funded in part through a CDC grant, provides information as well as referral services to over 65,000 callers a year (approximately 90 percent of the calls are related to STD infections other than gonorrhea or syphilis); ten Prevention/Training Centers are in operation and will provide clinical training for approximately 2,000 mid-career health care providers from the public as well as private sector.

Medical school/health department efforts (funded by project grants) to improve the STD didactic as well as clinical training of medical students.

## FLUORIDATION

Question: According to information provided during last year's hearings, 3 States had already indicated to CDC that they would not continue fluoridation activities after the categorical funding period terminated. Do you plan any followup studies on these States at any point in the future to determine the consequences of such action on dental health?

Answer: The Association of State and Territorial Health Officials has recently added considerable information about dental health to their national reporting system. In addition, individual States and the National Institute of Dental Research conduct surveys so information will continue to be available.

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## QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

### NIOSH MORGANTOWN FACILITIES

Question: As you know, I have a particular interest in the National Institute of Occupational Safety and Health facility located in Morgantown, West Virginia.

I was advised by the Centers for Disease Control last year that additional funding would be channeled into the Morgantown facility in FY 1985 for back injury research. Does this budget reflect this increase in funding for this activity at Morgantown?

Answer: The Institute has defined the Ten Leading Work-Related Diseases and Injuries and is using this list to focus its research program and resources in controlling these problems. Back injury research is a part of the NIOSH program for musculoskeletal injuries which is number 2 on this list. Therefore increased attention at the Morgantown facilities will be focused on back injury research in upcoming years. In FY 1982, the NIOSH program related to prevention of musculoskeletal injuries, including back injuries, consisted of five projects which cost 2.4 full-time equivalents (FTE) and $78,250. Additionally, two physical therapists were successfully recruited to supplement the research staff and to broaden the back injury research program. In FY 1983, 4.2 FTE and $56,225 were devoted to six projects that primarily dealt with evaluation of existing data and available injury prevention materials. The FY 1984 program includes 4.7 FTE and $120,550 committed to six projects that focus on new diagnostic methodologies, the basic science of muscle response to cumulative trauma, and development of work practices to prevent back injuries. Four of these projects have multiple year activity and resource commitments will be continued in FY 1985.

Question: Would you provide for the record, the types of research programs and activities currently taking place at the Morgantown facility as well as the dollar amounts dedicated to each activity and the number of FTE's assigned to each activity. I would also appreciate this same information for FY 1983 and what your FY 1985 budget projects at this facility in the coming fiscal year.

Answer: Two NIOSH Divisions, the Division of Respiratory Disease Studies (DRDS) and the Division of Safety Research (DSR) are located at the Morgantown facility. DRDS has the principle responsibility within the Institute for conducting clinical and epidemiological research studies on occupational respiratory diseases and for conducting occupational health research programs in the areas of energy, agriculture, and coal and non-coal mining. DSR is the focal point of the NIOSH Accident/Injury Prevention Research Programs. Primary responsibilities of the Division include developing a National data base of work related injuries, designing and conducting safety practices, developing performance criteria for respirators and other personal protective devices, and testing and certifying respirators.

The budgets and FTE's for these research programs are:

| | FY 1983 | | FY 1984 | | FY 1985 | |
|---|---|---|---|---|---|---|
| | Budget | FTE's | Budget | FTE's | Budget | FTE's |
| DSR | 3,493,000 | 70.7 | 3,598,000 | 69 | 3,598,000 | 68 |
| DRDS | 5,246,000 | 128.9 | 5,931,800 | 128 | 5,931,800 | 125 |

Question: Would you please provide the number of people on board at the Morgantown facility at the close of fiscal year 1983, and what you project for the end of FY 1984 and FY 1985.

Answer: At the end of FY 1983, there were 193 permanent employees on board at the Morgantown facility. Based on the FY 1984 and 1985 budget projections, we estimate a permanent employee ceiling of 203 for both fiscal years.

Question: Do you have any plans to move or transfer to or from this facility any activities in FY 1984 or FY 1985?

Answer: With the current budget projections, we plan neither to expand or diminish the research programs ongoing in the Morgantown facility.

Question: Would you also advise what the long-range plans are for activities at this facility for the next 3 fiscal years?

Answer: There are no anticipated changes in the level of effort of the two research divisions, although the nature of those efforts may change depending on program needs.

## QUESTIONS SUBMITTED BY SENATOR THOMAS EAGLETON

### NURSING HOMES UNCOMPENSATED CARE OBLIGATIONS

Question: Prior to 1979, nursing homes were able to meet their Hill-Burton obligations for a reasonable amount of uncompensated care by applying the difference between their true costs and their Medicaid reimbursement. In 1979, the Department of Health and Human Services issued new regulations overturning the previous policy and rendering nursing home compliance with the Hill-Burton program virtually impossible. In October 1982, regulations were again issued by the Department of Health and Human Services which, despite the Department's acknowledgement of problems, failed to deal with this nursing home issue.

Can you tell me if the Department is working toward issuing new regulations to address this problems. If not, I would appreciate your looking into the matter and advising the Committee as to the feasibility of an administrative resolution through exempting nursing homes from the 1979 rule change, allowing a facility to meet its obligation by maintaining a completely open door admissions policy, or by any other means which you may find upholds the spirit of the Hill-Burton requirement.

Answer: The Department agrees that current Hill-Burton regulations were designed with hospitals in mind. Because of this, we have evaluated the potential benefits of a number of possible adjustments to nursing home requirements. We are willing to work with your staff in addressing this issue. We feel strongly, however, that any changes should not result in a reduction in the amount of uncompensated care provided by nursing homes. We are also concerned that any solution to this problem not imply that State Medicaid rates for nursing homes are inadequate.

## ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

## STATEMENT OF ROBERT L. TRACHTENBERG, ACTING ADMINISTRATOR

**ACCOMPANIED BY:**

**LARRY B. SILVER, ACTING DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH**

**WILLIAM POLLIN, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE**

**ROBERT C. NIVEN, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM**

**ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### PREPARED STATEMENT

Senator EAGLETON. To conclude our hearing this morning we will hear testimony from the Alcohol, Drug Abuse, and Mental Health Administration. First we will have Mr. Robert L. Trachtenberg, Acting Administrator of ADAMHA, who will give us a summary of his prepared statement. He is accompanied by Messrs. Silver, Pollin, Niven, and Itteilag.

Following Mr. Trachtenberg, Dr. Silver will summarize his statement on behalf of Saint Elizabeths, and then we will have questions. Senator Weicker is going to return later on, and I understand Senator Proxmire has some questions.

Please proceed, Mr. Trachtenberg.

Mr. TRACHTENBERG. Mr. Chairman, it is pleasure to be here this morning.

With your permission, I would like to summarize the statement.

Senator EAGLETON. The full statement will appear in the record.

[The statement follows:]

## STATEMENT OF ROBERT L. TRACHTENBEG

It is a distinct pleasure to appear before you as Acting Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, to discuss the President's Fiscal Year 1985 budget request for Federal health programs in these disease areas.

The request before the Subcommittee today has been carefully prepared to capitalize on the highly promising research opportunities now before us as a result of the unprecedented advances of the past few years. This progress has included many achievements in uncovering fundamental information about the intricate functioning of the brain and nervous system, and has developed an impressive array of new research technologies. This record of research accomplishments, recognized by numerous prestigious research prizes and achieved with the steadfast support of this Subcommittee, gives us confidence that our momentum can continue unabated as we attempt to solve many-- even the most difficult --of the enigmas underlying alcohol, drug abuse, and mental health disorders.

Among the most recent achievements is the experimental development of several new drug and behavioral therapies which show an ameliorating effect on the memory loss that is a tragic hallmark in patients with Alzheimer's Disease. Work in our intramural research program has also shown that Alzheimer's Disease is often accompanied by abnormally high levels of aluminum in areas of the brain associated with memory and higher mental functions. If such an association is proven, it may provide an important clue to the diagnosis and treatment of this debilitating disease.

New and scientifically intriguing achievements have been made regarding opiate receptors and natural morphine-like substances which have made basic drug abuse research one of the most exciting and intensely followed fields of biological research. Following on discoveries made in the 1970's, at least a dozen endorphins and three kinds of opiate receptors have been identified recently which have important differences in their effects on pain and their location in the brain. Entirely new lines of research have been opened regarding their potential role in such areas as analgesia, drug dependence, euphoria and reward, stress, and the regulation of body temperature.

Significant progress also has been made in uncovering genetic patterns involved in predisposition to alcoholism and in elucidating the action of alcohol on the individual cell. Both are essential steps toward being able to design effective intervention and prevention actions for the victims of alcohol-related problems.

Mr. Chairman, the principal vehicle that has so successfully contributed to producing the continued expansion of insights into many health problems of our concern has been the investigator-initiated research project. In FY 1985 these projects will continue to be our main avenue for sustaining vigorous and high quality research on alcohol, drug abuse, and mental disorders. The budget request proposes sufficient funds to support 500 new and competing investigator-initiated research grants, an increase of 21 over the anticipated 1984 level.

In the aggregate, the average cost of each new and competing award would increase 4.5 percent over the FY 1984 average cost. In addition, 702 non-competing awards would be supported. Full indirect costs would be paid for research grants and cooperative agreements.

The overall research budget of the agency would increase by 6.3 percent above the 1984 level in the President's request for FY 1985. This is convincing evidence of the Administration's commitment--even in times of tight fiscal constraints and limited public resources--to continue the quest for solutions to health problems which today not only cost our society enormous sums of money, but also inflict devastating personal tragedy on millions of Americans and their families.

All three ADAMHA Institutes would share in the research increase requested by the President. It would raise the agency's total scientific investment to $289 million in FY 1985.

For mental health research, the budget request is $177.6 million, an increase of $3.3 million over 1984. The striking pace of brain research currently funded by NIMH was demonstrated this year in the award of the prestigious Albert Lasker Prize to the neurobiologist Dr. Eric Kandel, a long-term NIMH grantee at Columbia University. By examining neurophysiologic and neuroanatomic function at the cellular level of lower organisms, Dr. Kandel has provided an elegantly conceptualized and highly useful strategy for understanding the molecular events that control learning and the genetic factors that modify behavior.

The accomplishments in mental health research, of which this is only one example, are no accident. They are built upon the solid scientific foundations Congress has underwritten these many years. They represent the maturation of the many disciplines essential to understanding the fundamental causes of the mental illnesses, particularly through work in behavioral and brain research. The accomplishments also reflect the importance the National Institute of Mental Health has placed on the systematic assessment of the state of knowledge in critical research areas, and the focusing of research support in the key areas most likely to yield appreciable benefits in enhanced basic knowledge and application to clinical practice.

In FY 1985, the NIMH research program would place special emphasis on the serious mental illnesses such as schizophrenia and the depressive disorders, as well as Alzheimer's Disease, childhood disturbances, anxiety disorders, and stress. The Institute also would maintain its scientific program in the strategic area of epidemiology, and in prevention--with the hope ultimately of being able to help people avoid many of the mental and emotional problems which today interfere with millions of lives.

With respect to drug abuse research, the President's FY 1985 request is $63.5 million, an increase of $8.7 million. These funds would be used to make an additional 21 new awards and support ongoing research ranging from basic biomedical studies at molecular and cellular levels to applied research directed at developing improved treatments and effective school-based prevention programs for youth.

Through its newly established, formal neurosciences program, NIDA will fund studies next year on both the acute and chronic effects of drug abuse upon brain structure and function, as well as the biological basis for drug induced euphoria and other altered mood states. By supporting brain research that identifies the "reinforcement" mechanisms of drug abuse behavior, NIDA plans to expand its focus on investigations directed toward uncovering the common neural mechanisms of many compulsive disorders, including overeating, cigarette smoking, and drug abuse.

Among NIDA's highest priorities in FY 1985 would be a strong research emphasis on marijuana, including the drug's effect on the brain and the immune and reproductive systems, and its potential as a carcinogen. Recognizing the potential threat widespread marijuana use causes among youth, NIDA also will explore its possible adverse effects on lung and pulmonary function. While there is no direct evidence linking marijuana smoking to cancer, the "tar" of cannabis residuals can cause tumors in laboratory animals. Preliminary findings such as this, and the fact that changes in the levels of reproductive hormones have been seen following habitual marijuana use, lend an immediacy to our need for expanding this research program.

Turning to alcohol abuse and alcoholism, the President's budget proposes an increase of $5 million for research, for a total of $47.8 million devoted to scientific studies in this problem area.

Mr. Chairman, although very little alcohol research had been conducted prior to the 1970's, great strides have been made in the past decade in building a base of fundamental knowledge about alcoholism and alcohol abuse. The Federal research program in this area is founded on the premise that we must gain sufficient knowledge to reduce the tragic waste of lives and national resources caused by the abuse of alcohol.

Based upon recent research breakthroughs that document an inherited susceptibility to alcoholism in nearly one-half of those who develop the disease, NIAAA plans to expand its support of research aimed at identifying those biological traits which are inherited along with the susceptibility to alcoholism. This research will have great impact upon the prevention of alcoholism as well as the understanding of the biologic mechanisms that determine the onset of this disease. Numerous important clues have emerged from investigations of a variety of biological responses to alcohol. It has been learned, for example, that there are genetic differences in the way neurotransmitter systems in the brain respond to alcohol. Other clues are emerging from studies of alcohol metabolism and studies of alcohol's effect on the cell.

The deleterious effects of alcohol can be seen in almost every human physiologic system. Because of this, NIAAA will continue to support alcohol research that studies the effects of maternal drinking on the fetus, the impact of alcoholic parents upon their children, the role of alcohol in the development of organ-specific pathology such as liver or heart disease, and alcohol's effects on several forms of cancer.

Alcohol research in 1985 also would focus on gaining a better understanding of how attitudes toward drinking are shaped in our early years, and the process of initiation into alcohol use. The Institute's prevention research program will continue its efforts to identify precursors of "problem drinking" and how to prevent its development.

Mr. Chairman, in FY 1985 all three of our Institutes would devote particular attention to the association between alcohol, drug abuse, and mental health problems and the behavioral choices made by individuals which contribute to development of these illnesses. Further research knowledge about this relationship will put us in a better position to try to forestall these behaviors. I should point out that we have recently increased collaborative efforts with the NIH to stimulate research on encouraging healthy behaviors among our citizens and determining more precisely the role they play in improving one's health.

The 1985 request proposes to eliminate the community support program, a service demonstration conducted in 47 States to date. The demonstration period has ended and we expect the States to take the initiative to continue successful programs, basing them on the model we have developed and using their own funds or those they receive from other non-Federal sources.

Implementation of Reform 88 management initiatives in our intramural research programs is expected to achieve administrative efficiencies in FY 1985 without impairing the research endeavor. Direct operations accounts will experience similar efficiencies.

Research training activities in all three Institutes would continue at their 1984 levels under the President's budget. The number of trainees funded would drop from 1,096 to 982, primarily to accommodate a 5 percent stipend increase. Increased attention will be given to meeting critical needs for clinical investigators, epidemiologists, prevention research specialists, and minority scientists. In addition, we will continue a process begun in 1984 to examine systematically research training needs in relation to research opportunities and to training career and employment patterns.

Mental health clinical training is proposed for elimination in FY 1985, consistent with the previous phaseout of such activities in NIAAA and NIDA. The Administration believes that the mental health clinical training program has achieved its general goal of creating a large cadre of well-trained health professionals and that the small percentage of the total effort which had been supported by the Federal program should now be provided by other funding sources.

The President's budget also proposes that the Alcohol, Drug Abuse, and Mental Health Services Block Grant be centralized and consolidated with other block grants in the Office of the Assistant Secretary for

Health. Such consolidation will greatly improve the management of these essential programs.

I would be pleased to answer any questions the Subcommittee may have.

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## BIOGRAPHY OF ROBERT L. TRACHTENBEG

Date of Birth: February 17, 1937
Place of Birth: Brooklyn, New York

Married - 4 children

Fairleigh Dickinson University - 1957 - B.A.
New York Law School - LLB - 1959 (Law Review)
Admitted to practice in New York State and D.C.

9/83 - to present - Acting Administrator, Alcohol, Drug Abuse, and Mental Health Administration, Public Health Service, HHS.

7/82 - 9/83 - Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration, Public Health Service, HHS. Acts as alter ego to Administrator of the agency and serves as Acting Administrator when necessary, carrying out such public and internal functions as necessary; supervised the internal management of the Office of the Administrator to assure responsiveness to workload requirements, and satisfy requirements of the Assistant Secretary for Health and the Department. Assists in developing and implementing management and program systems and procedures to comply with agency policy priorities. Maintains continuing oversight of Institute activities to develop current awareness of key issues and to assist the Institute Directors in developing sound Institute policy.

10/81 - 7/82 - Acting Director, Office of Community Services. At the request of the Secretary, DHHS, on temporary assignment to establish and administer multi-faceted program of State block grants, discretionary programs and closeout of former CSA programs. Implemented creative fiscal, audit, and grants management practices to accomplish closeout of major anti-poverty agency. Demonstrated success in recovering large sums of Federal dollars from grantees.

5/79 - 10/81 - Deputy Administrator, Alcohol, Drug Abuse, and Mental Health Administration, Public Health Service, HHS. As Deputy Administrator, shared with the Administrator the responsibility for planning, managing, and providing the overall direction necessary for effective accomplishment of ADAMHA programs and activities. Particular focus was on development of management accountability systems and the setting of program of priorities for expenditure of $750 million annual budget.

1/75 - 5/79 - Associate Commissioner for Hearings and Appeals and Chairman of the Appeals Council for the Social Security Administration. Directed a 4,500 person organization. Was responsible for providing program and management direction over a decentralized hearings program and centralized appellate system. Employed over 650 administrative law judges. OHA is one of the largest systems of administrative justice in the Federal Government and one of the largest employees of attorneys.

9/73 - 1/75 - Deputy Assistant Secretary for Grants and Procurement Management in the Office of the Secretary, Deputy of Health, Education, and Welfare. Developed, promulgated and enforced all procurement and grant regulations and policy for the DHEW, including cost and audit policy and minority business. Supervised contractor protest procedures. Also monitored and evaluated performance of the more than 200 grant and procurement offices within the Department.

8/67 - 9/73 - Office of Economic Opportunity, Deputy General Counsel. Served in a variety of supervisory positions in the General Counsel's office, culminating with Deputy General Counsel. Specialized in procurement and grant law and all facets of legal and business management, including supervision of OEO's investigative operations.

7/60 - 8/67 - Department of the Army. Served in various positions in the Department of the Army, including 4-1/2 years in the Judge Advocate General's Corps and as a civilian trial attorney. Specialized in government procurement law and business and administrative law matters.

AWARDS:

| | |
|---|---|
| Recognition Award, William A. Jump Foundation | 1974 |
| Secretary's Citation, HEW | 1975 |
| Commissioner's Citation, Social Security Administration | 1976 |
| Secretary's Citation, HEW | 1977 |
| Commissioner's Citation, Social Security Administration | 1978 |
| Member, Administrative Conference of the United States | 1975-1979 |
| Senior Executive of Meritorious Rank Awarded by the President | 1980 |
| Senior Executive of Distinguished Rank Awarded by the President | 1982 |

### BUDGET REQUEST

Mr. TRACHTENBERG. Overall our research budget request for fiscal year 1985 increases by about $17 million. As you know, research is the primary focus of our agency.

### PROJECT GRANTS

The high priority area within the research budget is the project grant or the investigator-initiated award. The budget will permit us to do a number of things with respect to that particular high priority area.

The first thing is that we will get back up to 500 new and competing project grants. We think that this is very important. That figure is about the annual average that we have had for the past 10 years, and we have been working for the past several years to get back to the 500 level.

Senator EAGLETON. How low did it get?

Mr. TRACHTENBERG. Approximately 335.

Senator EAGLETON. Was that 5 or 6 years ago?

Mr. TRACHTENBERG. No; about 3 years ago.

We have been building back up and we are very pleased about that. This is where the strength of our program is and we are pleased that we can send a message to the investigators in the field that applications can be received and there will be adequate funding.

The budget also provides us the means to fully fund the indirect costs applicable to these grants, and it will permit us to fully meet our continuation obligations so that our researchers can continue their research unabated and without any sense of interruption in the program.

Last, we will be able to meet in a modest way the inflationary cost increases both for our new starts and in our continuation awards.

### RESEARCH EXCELLENCE

We believe the ADAMHA Research Program continues to be an area of excitement. The burgeoning of knowledge in the alcohol, drug, and mental health area is extremely exciting and it has been for the last several years. On top of that, the quality of ADAMHA research has improved remarkably over this period of time. Our research has become more rigorous from a methodological standpoint; the technology has become very sophisticated; and our scientists generally have become more productive.

I would like to point to just one rather simple but, I think, good indicator of this. In 1980 our priority score was about 257.

Senator EAGLETON. Your what score?

Mr. TRACHTENBERG. The priority score. We assess our grants on the basis of a numerical value on a range from 100 to 500, 100 being the best score, 500 being the poorest score. In 1980 we were funding at a 90-percentile score of about 257, which is a respectable payline level. We project in 1985 that this 90-percentile payline will be 167 or better. So you can see the steady decline in the number, which means that considerably better quality research will be funded.

### MEASURES OF SUCCESS

In many respects I think that the hallmark of the success in the ADM field is the greater specificity in the understanding of these disorders and diseases, both in being able to subtype different disorders that were thought at one point to be just one general disorder, and in being able to identify populations at risk. We are not only able to identify them, but also to come up with prevention interventions or treatment interventions specific to those particular populations and to be successful with them.

Another area is using a combination of psychosocial and pharmacological indicators to match treatment to individual patient needs.

### NEUROSCIENCES RESEARCH

I think the most exciting area is the development of the neurosciences area. This includes the identification of neurotransmitters and how they bind to specific receptor sites in the brain. That process has enormous and profound implications for the study of behavior, including the addiction process itself.

I should point out that the potential that we have in that area could not have been developed without the groundbreaking research that the National Institute of Mental Health and the National Institute on Drug Abuse have done over the years to identify these substances in the brain and discover the incredible pharmaceutical laboratory that in reality constitutes the brain.

### RESEARCH PROGRAM DEVELOPMENT

We haven't gotten to this point of development of the quality of our research by accident. It has come about through maturation of the various disciplines that have been doing research in this area, many in a multidisciplinary way; it has come about by the fact that a number of highly gifted and talented researchers from other fields, seeing the explosion of science in the ADM field, have come into this field; and it is largely due to the investment over the past 10 years in the research training effort which has developed this high quality pool of researchers.

On top of that, there has been a development of exotic and sophisticated technologies, such as the PET scan and other imaging techniques, that 10 or 15 years ago no one ever dreamed would be so invaluable in understanding the chemistry and the functioning of the brain.

Credit is also due to the boldness of the ADAMHA institutes themselves. They have made an effort to translate the technology into very bold and creative ways of moving money to where the opportunities are, not just supporting the old research line, but moving, sometimes at risk, to where the opportunities and the potential for breakthroughs really exist. Again, we are very pleased with our success.

## ADAMHA AWARDS

In the past 10 years ADAMHA intramural and extramural researchers have received numerous awards, including two Nobel prizes and three of the very coveted Lasker awards. We are also very pleased with their success as an indicator of the quality of our activities.

What has been accomplished over the past several years can only be matched by the opportunities we take advantage of as we move ahead.

We hope this committee, which has been so supportive of our activities in the past, will permit both the intramural and the extramural scientists to pursue the magnificent research that has already begun to understand the causes and the costs of these diseases, to discover the best treatments that are available both from a cost and an efficacy standpoint, and most importantly, to find ways to prevent these disorders from continuing and thereby reducing the high burden of illness that they represent.

Mr. Chairman, in other respects our budget is basically similar to what it was in fiscal year 1984. Our other research mechanisms are basically funded at about the same level. We do propose the elimination of funding for the Clinical Training Program and the Community Support Program, as we did last year. Proposed block grant funding increases by 2.2 percent, about $10 million.

I would now like to make myself and the Institute directors available for any questions that you may have.

Senator EAGLETON. Senator Proxmire has joined us. I think he has some questions, Mr. Trachtenberg, and I will yield to him at this time.

## UCLA STUDY

Senator PROXMIRE. Thank you very much, Mr. Chairman.

Last year the National Institute of Mental Health awarded approximately $650,000 to UCLA to study television's role in affecting socialization in the context of other family and child influences. That project focuses on families with children in the 7- to 15-year-old age bracket. Can you tell us how that study fits into the overall work of the Institute?

Mr. TRACHTENBERG. With your permission, Senator, I would like the Acting Director of NIMH to respond to that.

Dr. SILVER. This is a study that tried to look at the various cognitive models by which individuals learn socialization. The results are not in yet. This is a project that started in fiscal year 1983. We are hoping that this will help us better understand how television becomes another variable in the development of behavior patterns.

Prior to television most of the role models for learning how to handle feelings such as anger came from parents. The advent of television added another additional role model factor. The project was reviewed and thought to be of high quality. We think the results will be very meaningful to us in understanding how people learn to deal with feelings, how they express them, and the role of television in this context.

Senator PROXMIRE. How would you use the results of that study?

Dr. SILVER. If it shows any evidence of harmful influence, we would work with the industry, as we have done in the past. More importantly, I think it will give us some clues as to how we might use the medium in a positive way to help individuals learn how to deal with behavior.

### COLLABORATION WITH NSF

Senator PROXMIRE. Over the years there have been a great number of studies on the effect of television on children. To what extent do you cross check with the National Science Foundation to make sure that your grants in that area don't duplicate the work they have done? NSF has done a substantial amount of research in the area.

Dr. SILVER. The group of researchers in this area collaborate a great deal, and I will provide that answer for the record. We do have a linkage with the NSF.

Senator PROXMIRE. Give me what you can for the record.

Dr. SILVER. We will do that.

[The information follows:]

### NIMH/NSF COLLABORATION ON THE EFFECT OF TV ON CHILDREN

With the exception of studies concerning the effects of television advertising on children, most of the federally supported research on the behavioral influences and effects of the medium has been by the Department of Health and Human Services. The National Institute of Mental Health [NIMH] has served as the lead within the Department since 1969 when it became the host agency for the Surgeon General's Scientific Advisory Committee on Television and Social Behavior. The Surgeon General's committee investigated the causal connection between the viewing of televised violence and subsequent aggressive behaviors in children and adolescents and issued its report in 1972. Researchers since then have begun to study media influences and effects on behavioral aspects other than aggression and violence. The potential importance of television veiwing in shaping children's effective development and emotional behaviors, has become recently recognized and this area of study is now beginning to receive attention.

Investigators generally are aware that the NIMH has been an important source of support for key research on television influence on behavior and mental health. Most investigators seeking Federal grant support on these topics would apply, therefore, to NIMH. Some might, however, submit parallel or duplicate requests to the National Science Foundation [NSF]. Where this is done, Public Health Service grant applications require a listing of such parallel submissions as well as information on all existing investigator grant support. NIMH staff are regularly in contact with appropriate NSF staff members to discuss such applications and possible agency actions and coordination of informed funding decisions as the result.

### REVIEW GROUP WORK

Mr. TRACHTENBERG. That is one of the beauties of our study group process where we have the independent review groups. We bring in the highest quality experts in particular areas to review grant applications, and part of their responsibility is to know what is being investigated in other fields of science related to the areas that they are reviewing. Obviously it is not 100 percent effective, but it is one of the more important aspects of review group work.

Senator PROXMIRE. The effect of television on children seems to me to be something that we have studied often.

## UNIVERSITY OF MICHIGAN STUDY

Last year NIMH granted the University of Michigan about $160,000 for a study entitled "Social Judgement, Choice and Beliefs about Predictability."

The research summary indicates that "the research will have theoretical relevance for the understanding of the nature of evidence about subjective events and the ways in which people are similar and different in how they experience the world."

The research findings are expected to clarify issues central to attribution theory which are relevant to judgments individuals make in attributing symptoms of emotional and mental stress to particular causes.

How will the results of that research be used?

Dr. SILVER. The general area of behavioral science research is very interested in how people conceptualize their opinions and how this might be influenced by how much they have respect for or trust in the source. This was one of a number of studies looking at that issue. Again, it is hard when you are doing the basic research to have an absolute measurement of how the results will be used, but we think that this will again help us to understand how people form attitudes, how people form opinions, and based on that, perhaps some information about where to proceed. The results are not in yet. This was a study that was started in fiscal year 1983.

Senator PROXMIRE. The language of the research summary seems to be quite vague. I don't mean to demean and belittle this work, because it can be extraordinarily useful, but sometimes it does seem that we are just making an effort to keep the university community happy.

Dr. SILVER. Again, the project was reviewed by a group of outside peers who are experts in this area of cognitive research. They gave it a very high score as quality research. The second level review is the Mental Health Advisory Council, which also approved it. Both groups felt that this was a very worthwhile project.

## ALCOHOL PATIENT PLACEMENT SYSTEM

Senator PROXMIRE. On page 16 of your justifications you indicate that the National Institute on Alcohol Abuse and Alcoholism, in response to a committee directive, planned to collaborate with the Department of Defense on a randomized clinical trial study of selected approaches to alcoholism treatment. The committee directive called for research leading to a standardized patient placement system.

I'm concerned that a DOD-sponsored study would deal with an atypical group of alcoholics—young single men under military discipline. What makes you think such a study would help in the construction of a standardized patient placement system?

Dr. NIVEN. I think that the wording is unfortunate because it implies that there is a definitive agreement with the Department of Defense to do such a study. That is not the case.

We have reason to believe that we could indeed find some useful results that would be applicable to a significant percentage of the population by cooperating with the Defense Department on treatment outcome studies. But you are right that it would not be universally applicable.

The intended cooperative agreement with the Department of Defense is to explore the possibilities for doing research on a variety of alcoholism treatment outcomes. The first phase of that is a study to define what the benefits and costs would be, and what would be the best ways to proceed.

Senator PROXMIRE. I don't quarrel with the desirability of the Department of Defense doing a study of approaches to alcoholism treatment. I realize it's a real problem for the Department of Defense. It's probably more of a problem in Russia, for example, than in this country, but it's a problem here, too. There is nothing more important in a military force than to have competent people who are responsible, and I think that this study might help. As I say, my quarrel is with the argument that it would lead to a standardized patient placement system.

Dr. NIVEN. It would answer some of the questions. It certainly would not, could not, and is not intended to be the definitive answer to the question of patient placement.

## TEENAGE ALCOHOL ABUSE

Senator PROXMIRE. Dr. Niven, in a response for last year's record your Institute stated that the proportion of teenagers who abuse alcohol rose from 24 percent in 1970 to 29 percent in 1980, a very significant increase in 10 years. Do we have any facts or theories as to what caused the increase?

Dr. NIVEN. Yes; we do. In fact, an enormous number of theories and several facts give us leads about what caused the increase. One of the major difficulties in looking at such studies, particularly over time, is to try and determine which of the data represent what we call a real increase, an increased number of people actually abusing a substance versus an apparent increase. In my opinion, the data collectively, at this point in time, suggest that fortunately there has been some stabilization or plateauing in that rate of increase.

Senator PROXMIRE. What do the latest statistics show for 1984? Has the teenage alcohol abuse rate stabilized at 29 or 30 percent?

Dr. NIVEN. It's in that area. I can't quote you the exact figure at this point, but I would be glad to provide that for the record. There is a variety of other lines of evidence which suggest that for the general population there may be a stabilizing and perhaps a decrease in overall consumption levels.

[The information follows:]

### TEENAGE DRINKING

The most recent survey data are from the 1983 high school senior drug use survey. They indicate drinking practices are stable. Thus, we continue to estimate that about 30 percent of 10th to 12th graders are alcohol misusers.

### NIAAA EFFECTIVENESS

Senator PROXMIRE. Since the NIAAA was established by law in 1970 and since teenage alcoholism rose during the rest of the decade, couldn't it be argued that your past efforts in this area have been ineffective?

Dr. NIVEN. I guess it could be argued, but we believe that we have made major progress in understanding a lot of the reasons for alcohol abuse and developing appropriate treatment and prevention during the last decade. Certainly there has been in the decade that you cite an increase in the number of young people using, the number of young people abusing, and the number of young people we believe who are actually dependent upon alcohol. It is clear that much more work needs to be done to understand and develop prevention efforts to lower those numbers.

### MARIJUANA USE

Senator PROXMIRE. Dr. Pollin, last year we were told for the record that the percentage of Americans over 12 years of age who had used marijuana at some time increased from 25 percent in 1977 to 31 percent in 1982. Why hasn't your Institute been able to have a greater impact on marijuana use?

Dr. POLLIN. Actually we think that there has been a significant leveling off and reduction in the use of marijuana and the use of drugs in general by young people.

We will be glad to provide details for the record.

[The information follows:]

## TRENDS IN DRUG USE

Numbers are percents

### MARIJUANA

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 52.8 | 56.4 | 59.2 | 60.4 | 60.3 | 59.5 | 58.7 | 57.0 |
| Used in Past Year.... | 44.5 | 47.6 | 50.2 | 50.8 | 48.8 | 46.1 | 44.3 | 42.3 |
| Used in Past Month... | 32.2 | 35.4 | 37.1 | 36.5 | 33.7 | 31.6 | 28.5 | 27.0 |
| Used Daily/Past Month | 8.2 | 9.1 | 10.7 | 10.3 | 9.1 | 7.0 | 6.3 | 5.5 |

### COCAINE

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 9.7 | 10.8 | 12.9 | 15.4 | 15.7 | 16.5 | 16.0 | 16.2 |
| Used in Past Year.... | 6.0 | 7.2 | 9.0 | 12.0 | 12.3 | 12.4 | 11.5 | 11.4 |
| Used in Past Month... | 2.0 | 2.9 | 3.9 | 5.7 | 5.2 | 5.8 | 5.0 | 4.9 |
| Used Daily/Past Month | .1 | .1 | .1 | .2 | .2 | .3 | .2 | .2 |

### SEDATIVES 1/

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 17.7 | 17.4 | 16.0 | 14.6 | 14.9 | 16.0 | 15.2 | 14.4 |
| Used in Past Year.... | 10.7 | 10.8 | 9.9 | 9.9 | 10.3 | 10.5 | 9.1 | 7.9 |
| Used in Past Month... | 4.5 | 5.1 | 4.2 | 4.4 | 4.8 | 4.6 | 3.4 | 3.0 |
| Used Daily/Past Month | .2 | .2 | .2 | .1 | .2 | .2 | .2 | .2 |

1/ Does not include drugs prescribed by physicians.

### TRANQUILIZERS 1/

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 16.8 | 18.0 | 17.0 | 16.3 | 15.2 | 14.7 | 14.0 | 13.3 |
| Used in Past Year.... | 10.3 | 10.8 | 9.9 | 9.6 | 8.7 | 8.0 | 7.0 | 6.9 |
| Used in Past Month... | 4.0 | 4.6 | 3.4 | 3.7 | 3.1 | 2.7 | 2.4 | 2.5 |
| Used Daily/Past Month | .2 | .3 | .1 | .1 | .1 | .1 | .1 | .1 |

1/ Does not include drugs prescribed by physicians.

### STIMULANTS 1/

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 22.6 | 23.0 | 22.9 | 24.2 | 26.4 | 32.2 | 35.6 | 35.6 |
| Used in Past Year.... | 15.8 | 16.3 | 17.1 | 18.3 | 20.8 | 26.0 | 26.1 | 24.6 |
| Used in Past Month... | 7.7 | 8.8 | 8.7 | 9.9 | 12.1 | 15.8 | 13.7 | 12.4 |
| Used Daily/Past Month | .4 | .5 | .5 | .6 | .7 | 1.2 | 1.1 | 1.1 |

1/ Does not include drugs prescribed by physicians.

Numbers are percents

HALLUCINOGENS

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 15.1 | 13.9 | 14.3 | 14.1 | 13.3 | 13.3 | 12.5 | 11.9 |
| (Adjusted for PCP) | | | | 18.6 | 15.7 | 15.7 | 15.0 | 14.7 |
| Used in Past Year.... | 9.4 | 8.8 | 9.6 | 9.9 | 9.3 | 9.0 | 8.1 | 7.3 |
| (Adjusted for PCP) | | | | 12.8 | 10.6 | 10.1 | 9.3 | 9.3 |
| Used in Past Month... | 3.4 | 4.1 | 3.9 | 4.0 | 3.7 | 3.7 | 3.4 | 2.8 |
| (Adjusted for PCP) | | | | 5.5 | 4.4 | 4.4 | 4.3 | 3.8 |
| Used Daily/Past Month | .1 | .1 | .1 | .1 | .1 | .1 | .1 | .1 |
| (Adjusted for PCP) | | | | .2 | .2 | .1 | .2 | .2 |

CIGARETTES

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 75.4 | 75.7 | 75.3 | 74.0 | 71.0 | 71.0 | 70.1 | 70.6 |
| Used in Past Year.... | NA | NA | NA | NA | NA | NA | NA | NA |
| Used in Past Month... | 38.8 | 38.4 | 36.7 | 34.4 | 30.5 | 29.4 | 30.3 | 30.3 |
| Used Daily/Past Month | 28.8 | 28.8 | 27.5 | 25.4 | 21.3 | 20.3 | 21.1 | 21.2 |

INHALANTS

| | CLASS OF | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Highschool Survey: | 1976 | 1977 | 1978 | 1979 | 1980 | 1981 | 1982 | 1983 |
| Ever Used............ | 10.3 | 11.1 | 12.0 | 12.7 | 11.9 | 12.3 | 12.8 | 13.6 |
| (Adjusted) | | | | 18.7 | 17.6 | 17.4 | 18.0 | 18.8 |
| Used in Past Year.... | 3.0 | 3.7 | 4.1 | 5.4 | 4.6 | 4.1 | 4.5 | 4.3 |
| (Adjusted) | | | | 9.2 | 7.8 | 6.0 | 6.6 | 6.7 |
| Used in Past Month... | .9 | 1.3 | 1.5 | 1.7 | 1.4 | 1.5 | 1.5 | 1.7 |
| (Adjusted) | | | | 3.1 | 2.7 | 2.3 | 2.5 | 2.7 |
| Used Daily/Past Month | .0 | .0 | .1 | .0 | .1 | .1 | .1 | .1 |
| (Adjusted) | | | | .1 | .2 | .2 | .2 | .2 |

(Adjusted figures for amyl and butylnitrites not available for 1975 - 1978)

MARIJUANA

| Household Survey | ESTIMATED PERCENT OF THE POPULATION | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used | 14.0% | 23.0% | 22.4% | 28.0% | 30.9% | 27.3% |
| Used in Past Year | NA | 18.5% | 18.4% | 22.3% | 24.1% | 20.7% |
| Used in Past Month | 7.0% | 12.0% | 12.3% | 16.6% | 16.7% | 11.1% |
| Age 18-25 | | | | | | |
| Ever Used | 47.9% | 52.7% | 52.9% | 59.9% | 68.2% | 64.3% |
| Used in Past Month | NA | 34.2% | 35.0% | 38.7% | 46.9% | 40.7% |
| Used in Past Year | 27.8% | 25.2% | 25.0% | 27.4% | 35.4% | 27.5% |
| Age 26 and Above | | | | | | |
| Ever Used | 7.4% | 9.9% | 12.9% | 15.3% | 19.6% | 23.4% |
| Used in Past Month | NA | 3.8% | 5.4% | 6.4% | 9.0% | 10.8% |
| Used in Past Year | 2.5% | 2.0% | 3.5% | 3.3% | 6.0% | 6.7% |

COCAINE

| Household Survey | ESTIMATED PERCENT OF THE POPULATION | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used | 1.5% | 3.6% | 3.4% | 4.0% | 5.4% | 6.9% |
| Used in Past Year | 1.5% | 2.7% | 2.3% | 2.6% | 4.2% | 4.3% |
| Used in Past Month | .6% | 1.0% | 1.0% | .8% | 1.4% | 1.8% |
| Age 18-25 | | | | | | |
| Ever Used | 9.1% | 12.7% | 13.4% | 19.1% | 27.5% | 28.7% |
| Used in Past Year | NA | 8.1% | 7.0% | 10.2% | 19.6% | 19.5% |
| Used in Past Month | NA | 3.1% | 2.0% | 3.7% | 9.3% | 7.1% |
| Age 26 and Above | | | | | | |
| Ever Used | 1.6% | .9% | 1.6% | 2.6% | 4.3% | 8.7% |
| Used in Past Year | NA | NA | .6% | .9% | 2.0% | 3.9% |
| Used in Past Month | NA | NA | NA | NA% | .9% | 1.2% |

STIMULANTS

| Household Survey | ESTIMATED PERCENT OF THE POPULATION (1) | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used | 4.0% | 5.0% | 4.4% | 5.2% | 3.4% | 6.5% |
| Used in Past Year | NA | 3.0% | 2.2% | 3.7% | 2.9% | 5.5% |
| Used in Past Month | NA | 1.0% | 1.2% | 1.3% | 1.2% | 2.5% |
| Age 18-25 | | | | | | |
| Ever Used | 12.0% | 17.0% | 16.6% | 21.2% | 18.2% | 18.1% |
| Used in Past Year | NA | 8.0% | 8.8% | 10.4% | 10.1% | 11.1% |
| Used in Past Month | NA | 3.7% | 4.7% | 2.5% | 3.5% | 4.9% |
| Age 26 and Above | | | | | | |
| Ever Used | 3.0% | 3.0% | 5.6% | 4.7% | 5.8% | 6.4% |
| Used in Past Year | NA | NA | .8% | .8% | 1.3% | 1.8% |
| Used in Past Month | NA | NA | NA | .6% | .5% | .5% |

1/ Change in interviewing techniques makes this data noncomparable.

SEDATIVES

| Household Survey | ESTIMATED PERCENT OF THE POPULATION (1) | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used........... | 3.0% | 5.0% | 2.8% | 3.1% | 3.2% | 6.1% |
| Used in Past Year... | NA | 2.0% | 1.2% | 2.0% | 2.2% | 3.6% |
| Used in Past Month.. | NA | 1.0% | NA | .8% | 1.1% | 1.3% |
| Age 18-25 | | | | | | |
| Ever Used........... | 10.0% | 15.0% | 11.9% | 18.4% | 17.0% | 18.6% |
| Used in Past Year... | NA | 4.2% | 5.7% | 8.2% | 7.3% | 8.4% |
| Used in Past Month.. | NA | 1.6% | 2.3% | 2.8% | 2.8% | 2.5% |
| Age 26 and Above | | | | | | |
| Ever Used........... | 2.0% | 2.0% | 2.4% | 2.8% | 3.5% | 4.8% |

1/ Change in interviewing techniquest makes this data noncomparable.

TRANQUILIZERS

| Household Survey | ESTIMATED PERCENT OF THE POPULATION (1) | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used........... | 3.0% | 3.0% | 3.3% | 3.8% | 4.1% | 4.8% |
| Used in Past Year... | NA | 2.0% | 1.8% | 2.9% | 2.7% | 3.0% |
| Used in Past Month.. | NA | 1.0% | 1.1% | .7% | .6% | .8% |
| Age 18-25 | | | | | | |
| Ever Used........... | 7.0% | 10.0% | 9.1% | 13.4% | 15.8% | 14.8% |
| Used in Past Year... | NA | 4.6% | 6.2% | 7.8% | 7.1% | 5.9% |
| Used in Past Month.. | NA | 1.2% | 2.6% | 2.4% | 2.1% | 1.5% |
| Age 26 and Above | | | | | | |
| Ever Used........... | 5.0% | 2.0% | 2.7% | 2.6% | 3.1% | 3.6% |
| Used in Past Year... | NA | NA | 1.2% | 1.1% | .9% | 1.1% |

1/ Change in interviewing technique makes these data noncomparable.

INHALANTS

| Household Survey | ESTIMATED PERCENT OF THE POPULATION | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used............ | 6.4% | 8.5% | 8.1% | 9.0% | 9.8% | NA |
| Used in Past Year.... | 2.9% | 2.4% | 2.9% | 2.2% | 4.6% | NA |
| Used in Past Month... | 1.0% | .7% | .9% | .7% | 2.0% | NA |
| Age 18-25 | | | | | | |
| Ever Used............ | NA | 9.2% | 9.0% | 11.2% | 16.5% | NA |
| Used in Past Year.... | NA | 1.2% | 1.4% | 1.7% | 3.8% | NA |
| Used in Past Month... | NA | NA | .5% | NA | 1.2% | NA |
| Age 26 and Above | | | | | | |
| Ever Used............ | NA | 1.2% | 1.9% | 1.8% | 3.9% | NA |

* Data not collected in 1982

| CIGARETTES<br>Household Survey | ESTIMATED PERCENT OF THE POPULATION | | | | | |
|---|---|---|---|---|---|---|
| | 1972 | 1974 | 1976 | 1977 | 1979 | 1982 |
| Age 12-17 | | | | | | |
| Ever Used........... | NA | 52.0% | 45.5% | 47.3% | 54.1% | 49.9% |
| Used in Past Year... | NA | NA | NA | NA | 13.3% | 14.2% |
| Used in Past Month.. | NA | 25.0% | 23.4% | 22.3% | 12.1% | 12.4% |
| Age 18-25 | | | | | | |
| Ever Used........... | NA | 68.8% | 70.1% | 67.6% | 82.8% | 76.3% |
| Used in Past Year... | NA | NA | NA | NA | 46.7% | 41.1% |
| Used in Past Month.. | NA | 48.8% | 49.4% | 47.3% | 42.6% | 37.8% |
| Age 26 and Above | | | | | | |
| Ever Used........... | NA | 65.4% | 64.5% | 67.0% | 83.0% | 78.6% |
| Used in Past Year... | NA | NA | NA | NA | 39.7% | 37.3% |
| Used in Past Month.. | NA | 39.1% | 38.4% | 38.7% | 36.9% | 34.1% |

## STATE SURVEYS

Dr. POLLIN. There are two major national surveys and any number of individual State surveys which all show that there were peaks in the years 1978–79 with regard to overall levels of the use of most drugs and that since then drug use, particularly by young people, has been declining.

Senator PROXMIRE. Well, there seems to be a contradiction in the statistics here. Last year in a response for the record you said that in 1977 25 percent of those over the age of 12 had used marijuana and that a 1982 survey showed that 31 percent of those over the age of 12 had at some time used marijuana. So it looks as if between 1977 and 1982 you had a substantial increase in marijuana use. It went from 25 to 31 percent over that period.

Dr. POLLIN. As you pointed out, that increase referred to the number of people who had ever used it. The so-called lifetime prevalence includes use on one occasion or more. The much more important figures have to do with levels of current use, use during the past 30 days, and even more important those levels of use which are particularly damaging—daily use. Both of those levels of use decreased from 1978–79. Daily use among high school seniors was at 11 percent in 1978, and in 1983 has come down to less than half of that; it is now about 5.5 percent.

## TEENAGE ALCOHOL VERSUS MARIJUANA USE

Senator PROXMIRE. There is a common notion that there has been a leveling off or maybe a decline in marijuana use and that it corresponds with an increase in the abuse of alcohol. Has there been less reliance on marijuana accompanied by more reliance on liquor?

Dr. POLLIN. No; we interpret our data to show quite conclusively that there is not this kind of replacement phenomenon going on. During the 10-year period when the daily use of marijuana was doubling among high school seniors, the daily use of alcohol among high school seniors remained essentially level. During the past 5 or 6 years when both current and daily use of marijuana and most other drugs has been coming down there has not been any compensating increase in terms of the use of alcohol.

As Dr. Niven pointed out, the most recent data suggest that during the past year or two there has been some total national decline in the consumption of all alcohol.

## DIETARY GUIDELINES ON ALCOHOL

Senator PROXMIRE. In February, Dr. Niven, the Department of Agriculture and HHS published proposed new dietary guidelines on alcohol. The current guidelines state that one to two drinks daily appear to cause no harm to adults. The new guidelines state absolutely that no harm is caused and add that two drinks a day may actually be beneficial to nonpregnant adults.

Have you seen these guidelines? Do you believe it is appropriate for a Government agency to in fact suggest alcohol is beneficial?

Dr. NIVEN. We have not seen an official copy of the guidelines you refer to. We too have heard of such guidelines through attention they have received in several publications. We would indeed have some concern, based upon the available scientific evidence, about the appropriateness and the accuracy of what we have heard about them.

Mr. TRACHTENBERG. The agency has not been requested to comment on those guidelines yet.

Senator PROXMIRE. Does that mean that you cannot comment?

Mr. TRACHTENBERG. No; but we haven't yet reviewed them in order to comment.

Senator PROXMIRE. You're the experts in this area. It seems to me that this is an important public health question. The guidelines, for instance, drop any reference to alcohol-related illnesses. Do you believe that is wise?

Dr. NIVEN. We anticipate being formally asked to comment on these guidelines. From what I've heard, I question whether the guidelines drop all references to alcohol-related illnesses. We have also heard that there are a variety of recommendations pertinent to alcohol.

Senator PROXMIRE. Fine. Would you give that information to us for the record, because I am advised that they did drop all references to alcohol-related diseases? If I am wrong I would like to know.

[The information follows:]

## DIETARY GUIDELINES ON ALCOHOL

In 1980 the Departments of Agriculture and the then Health, Education and Welfare issued dietary guidelines for Americans which included information and views on alcohol—among them, "if you drink alcohol, do so in moderation."

In response to the Senate Committee Appropriations request in November 1981 to update these guidelines, the Secretary of Agriculture appointed the Dietary Guidelines Advisory Committee comprised of three members from the Department of Health and Human Services, three members from the National Academy of Sciences, and three members from the Department of Agriculture. Two public meetings to consider these guidelines were held in July and December 1983 and a third one is scheduled in Washington DC, on May 20 and 23. A final report is expected later this year.

At the moment, the National Institute on Alcohol Abuse and Alcoholism is reviewing and summarizing the most recent research on alcohol that would be relevant to the deliberations of the Dietary Guidelines Advisory Committee and plans to make these findings available to that committee prior to the May 20 meeting.

### EVALUATION INCREASE

Senator PROXMIRE. At any rate, your agency was not involved in rewriting the guidelines?

Mr. TRACHTENBERG. That is correct.

Senator PROXMIRE. I have one more question. According to your justifications your obligations for evaluation consulting services will increase from $869,000 in fiscal year 1983 to $2,430,000 in fiscal year 1984. That is an increase of about 300 percent in 1 year. Why is that?

Mr. TRACHTENBERG. That figure is only an estimate at this point. We work on the basis of a 1-percent evaluation set-aside in our legislation, and our proposed expenditures are somewhat less than 1 percent. In addition, as other priority areas of research start taking precedence during the year, our actual evaluation expenditures will go down from our initial plan.

Senator PROXMIRE. You set aside 1 percent of what budget?

Mr. TRACHTENBERG. Approximately 1 percent of the total agency budget.

Senator PROXMIRE. Your research funding hasn't gone up in the same proportion, it hasn't gone up threefold, has it?

Mr. TRACHTENBERG. No; but the high likelihood is that we are not going to spend anything close to $2.4 million on evaluation.

### 1984 EVALUATION EXPENDITURES

Senator PROXMIRE. In 1984 you will not spend $2,430,000?

Mr. TRACHTENBERG. No.

Senator PROXMIRE. You will be closer to the $869,000 figure?

Mr. TRACHTENBERG. Yes; we will.

Senator PROXMIRE. Why do you have the higher figure in your justifications?

Mr. TRACHTENBERG. We built in an estimate based on a plan devised early in the year. As I said, that gets modified as the year progresses and other priorities take over.

Senator PROXMIRE. That estimate is not very useful as a guideline.

Mr. TRACHTENBERG. After I saw it I was concerned also that it was as high as it was. But recently there has been greater attention being paid in our agency to the entire evaluation area. I think that evaluating our programs is important.

Senator PROXMIRE. Thank you very much.

Thank you, Mr. Chairman.

Senator EAGLETON. Thank you, Senator Proxmire.

### INTRAMURAL POSITION REDUCTION

Mr. Trachtenberg, I have a few questions for you, and then we will hear from Dr. Silver on Saint Elizabeths.

The budget justification for NIMH indicates that "the Intramural Program will absorb the major portion of this mandatory cost increase through a reduction of 29 full-time permanent positions."

What kinds of employees in what program areas will be affected if that reduction of 29 positions goes forward.

Mr. TRACHTENBERG. It is difficult to identify the exact categories of employees that will be affected. We hope to be able to make the reduction through a combination of attrition, retirement, and by elimination of two particular research activities that have not met the standards of peer review conducted by the Board of Scientific Counselors for the Intramural Program.

Senator EAGLETON. What are those two?

Mr. TRACHTENBERG. The Clinical Infant Development Program and the Plant Biology Program.

Senator EAGLETON. So eliminating those two programs and then attrition, which includes retirement, et cetera, you think will do it?

Mr. TRACHTENBERG. Yes; we are very hopeful at this point that it will not be necessary to have a reduction in force or anything of that nature in the Intramural Program.

### POSITION RESTORATION

Senator EAGLETON. Well, why did the NIMH professional judgment budget recommend the restoration of the 29 positions, in their words, "to assure the maintenance of a continuing level of effort in ongoing research programs?"

Mr. TRACHTENBERG. I am not sure I know what the professional judgment budget is.

Senator EAGLETON. Here is what is called the professional judgment budget for mental health research at the National Institute of Mental Health. It is not a document of the NIH, but I gather—and I am no expert on it—it is sort of a group recommendation that comes in part from folks who are in some way affiliated with NIH, professional interest groups, and the like.

Mr. TRACHTENBERG. I really haven't had a chance to look at it, Mr. Chairman. It is fair to say that it is going to be tight meeting the requirements of the budget, but we think we can do it. We are trying to balance our own needs with the needs of other public health service agencies and, obviously, the broader issues of the allocation of resources overall for the Federal Government.

I wouldn't deny the fact that an exemplary program like the Intramural Program of NIMH would be somewhat pressed to meet these requirements, but we think we can still meet them.

### IMPACT ON RESEARCH STAFF

Senator EAGLETON. Referring to these 29 positions, will there be any impact on senior and junior research staff?

Mr. TRACHTENBERG. There may be some people who must move around to other assignments, particularly the people related to the two programs that I mentioned. We are very hopeful at this point that there will not be any people in the Intramural Program who have to go out the door, however.

Senator EAGLETON. It's a hope, but you can't guarantee it?

Mr. TRACHTENBERG. I can't guarantee it, because a lot will depend on how accurate our estimates of attrition are.

Senator EAGLETON. What might be the effect on research support activities on specific areas of research effort?

Mr. TRACHTENBERG. There will be a tightening up, but I think the basic functions of the Intramural Program will continue as successfully as they have.

Senator EAGLETON. Would an increase of $2,175,000 in the intramural research appropriation obviate the need for this reduction?

Mr. TRACHTENBERG. That amount of money must relate to some of the mandatory cost increases, like that of the NIH management fund, that had to be absorbed. It would make life easier, but I still stand by the President's budget.

Senator EAGLETON. Mr. Trachtenberg, we hear before this committee and all other appropriations subcommittees frequently the statement that, well, don't worry, attrition is going to take care of it and we will continue to render just as good service, we'll not skip a beat, nobody is going to be hurt, and the quality of service or research will not suffer, and what have you. Are you certain, as you seem to be, that this cut of 29 positions can be as readily absorbed as you seem to project?

Mr. TRACHTENBERG. I can't give you, Mr. Chairman, an absolute assertion. We are experiencing new ground, particularly in the Intramural Program. You never know at what point a reduction cannot be handled by improved management efficiencies and when you start cutting it to the bone. My own sense—I've been around the Government a long time and have had a lot of experience in this area—is that we can handle it in the Intramural Program without cutting to the bone. Whether I can say the same for the next reduction, I don't know. But at this point I think we can handle it.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator EAGLETON. Mr. Trachtenberg and gentlemen, we have a series of other questions for practically everyone of you here. We will send them to you in writing and would like to have the answers back in writing as part of the record.

Mr. TRACHTENBERG. We will be pleased to.

Senator EAGLETON. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### RESEARCH GRANT FLUCTUATIONS

Question: The average number of new and competing grant awards made for NIMH over the 10-year period 1974-1983 was 318. 1974 was the high year with 444 awards--1983, the low with 201. For 1984 and 1985 you project 277 awards each year.

What is the practical effect of this roller coaster in your research program?

Answer: The instability of the annual number of grants awarded creates problems for the research programs of the Institute and the agency. Without some stability and predictability in the number of awards made, the research community feels less secure in their prospects to receive continuing or new support for their research ideas. This in turn reduces a researcher's incentive to (1) focus on ADAMHA research issues, as opposed to those of other organizations supporting biomedical and behavioral research; (2) invest the time and considerable effort necessary to develop a high-quality research application; (3) move into new areas of ADAMHA concern where the methodology may be less developed and therefore the competitive advantage lessened; and (4) focus on the future ramifications and practical application of his current research, as the need to secure stable future funding becomes of increasing concern.

The practical result is that we see fairly dramatic swings in the number and type of applications received in the agency. As investigators seek other sources of support they may turn to other research areas. Fewer project applications are received in emerging new interest areas. Applications from junior scientists tend to receive lower priority scores and these are not considered for funding. It may not be possible to reverse the impact of a "downswing" by a larger number of new and competing awards in the subsequent years. It may take several years of consistently strong research to develop and maintain a healthy research base. In the last couple of years ADAMHA has attempted to stabilize support for 500 new and competing grants in order to avert such fluctuations in subsequent years.

### APPROVED UNFUNDED APPLICATIONS

Question: What is the extent of approved but unfunded grant applications?

Answer: In 1985, we anticipate that there will be 426 approved but unfunded applications, with 117 having priority scores of 200 or better.

### CLINICAL TRAINING

Question: Once again no funds are requested to continue the Clinical Training Program. Last year when Congress approved $20.7 million for this activity, it directed the funds to be used to increase personnel in shortage specialties, training in child and geriatric mental health and minority support among other national priorities.

Is it your understanding that there no longer are shortages of personnel in some areas, or among some groups, or in some specialties?

Answer: No. I would agree that shortages still exist in some of these areas. It is, however, our belief that the States and universities are capable of training personnel in these areas without Federal support.

Question: What impact has the reduction in clinical training funds had on the four professions?

Answer: We know from testimony of the American Psychological Association to the Commission on Human Resources of the National Academy of Science; from the National Research Council's summary report, Doctorate Recipients from U.S. Universities; from the Council of Social Work Education's Statistics on Social Work Education in the U.S.; and from the National League for Nursing's Data Book that there has been some reduction in enrollment in and graduation from training programs in the mental health disciplines. This may not bear any relationship to a reduction in clinical training funds since those funds are currently available and will remain available through 1984.

Question: We keep hearing of a potential shortage in the number of psychiatrists.

What is the extent of this problem and where are the shortages most likely to occur?

Answer: The Graduate Medical Education National Advisory Committee (GMENAC) projected a shortfall of 8,000 psychiatrists and 4,900 child psychiatrists by 1990, in spite of an overall surplus of physicians. If these shortages materialize they would most likely be felt in public facilities, rural and inner city areas, and in work with the elderly and, especially, children.

Question: What is the situation in the other disciplines: psychology, social work and nursing?

Answer: There appears to be no overall shortage of psychologists or social workers, although there are shortages of personnel in these disciplines in some geographic areas, particularly rural or inner city, and in specialty areas such as geriatric or child mental health. The Institute of Medicine found a shortage of master's level nurses in all specialties. Finally, there is an insufficient supply of minority mental health professionals in all the disciplines.

## RESEARCH TRAINING

Question: In addition to eliminating the Clinical Training Program, the budget request would hold research training funds to last year's level -- resulting in a 13% reduction in the number of awards.

In your opinion is there a need to introduce some stability to this program?

Answer: From the point of view of prospective research trainees, educational organizations providing the milieu for their training, and organizations supporting investigator-initiated projects such as ADAMHA, it is indeed beneficial to provide stabilized funding of research training programs. This approach must assume nearly idealized conditions, however; significant questions have been raised not only about the proper level at which to stabilize support, but necessary adjustments to take into account such considerations as future Federal funding support, movement of researchers from other disciplines, changes in nationwide training capacity. While we have not developed a stabilization figure for ADAMHA, we are confident that the 1985 request includes sufficient support to ensure an adequate base of research scientists for the near term. One reason for this belief is that we continue to receive many more highly-rated research grant applications from these scientists than we are able to support with the grant funds available.

## RESEARCH TRAINING GRANTS

Question: Are you at all concerned that fewer training grants will result in less research in the future?

Answer: We feel that we have a level of training support which will produce a continuing supply of new researchers. We would only be concerned about the number and quality of these new scientists if there were a further reduction in our budget.

## REDUCTIONS IN INTRAMURAL STAFF

Question: Over and over again we have heard that we are on the threshold of discovery with respect to the workings of the brain. The budget includes about a 7 percent reduction in intramural research staff which "...should not seriously impede effective ongoing research operations.".

Is this really the time to cut your research staff?

Answer: The Intramural Research Program periodically evaluates the efficacy and continuing need for its research activities. Reductions in the Intramural Research Program will be limited to those studies whose research objectives are of lesser importance to the current scientific goals of the program. Ongoing programs working on critical brain research will not be affected by the reduction.

Question: What effect will this have on new initiatives as well as ongoing projects?

Answer: No cuts will be made on programs whose research is determined to be at a high level of quality.

## CSP SUPPORT

Question: Isn't this the sort of project that merits Federal support because these demonstration projects are designed to provide long-term alternatives which are community based for the care of the mentally ill?

Answer: Our review and evaluation of this program indicates that great progress has been made on the initial goal of stimulating the States to put more resources into community programs for the chronically mentally ill. Many of the original 19 States that have had demonstration projects for several years have clarified State and local level functions with regard to responsibilities for the chronically mentally ill and have generally earmarked increased resources for this population. There are several examples across the country of community support systems that have been developed and are effectively functioning as demonstrations within their States and regions. Wisconsin, Florida, and Oregon are examples of effective statewide systems for services to the chronically mentally ill.

By the end of FY 1984 we expect to have funded Community Support Program projects in all 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. Therefore, it is anticipated that the concepts of community support systems are being demonstrated all across the country. A number of States are beginning to see improved and expanded services for the chronically mentally ill as their major mission and give these needs the highest priority for utilization of State revenues and Alcohol and Drug abuse and Mental Health Services Block Grant funds. Having achieved this degree of success, it is felt that this program's benefits have been adequately demonstrated and that further Federal support is not warranted. While there are many programs such as this that can have desirable results, it is not believed that, in this period of limited fiscal resources, they have sufficient priority to merit Federal support.

Question: Am I wrong in stating that on the whole the demonstration projects have been quite successful?

Answer: We believe that through the projects described above, we have on the whole successfully demonstrated the concepts of the community support program.

## COMMUNITY SUPPORT PROGRAM

Question: I note that again there is no budget request for the Community Support Program for the chronically mentally ill. Is this a decision made within the Department or at OMB?

Answer: Research efforts, in particular the support of 500 new and competing awards, continue to remain our highest funding priority. Because of competing priorities it is believed that limited Federal resources should be focussed on research and associated research training programs rather than services demonstration efforts such as the community support program (CSP). We therefore prefer to maintain strong support for research, the primary mission of this agency.

## DRUG ABUSE BUDGET INCREASES

Question: You are requesting an increase of $8,773,000 - or 16 percent above last year's level for drug abuse research. If approved by Congress, this would mark a 33 percent increase in your research program over a two-year period.

At a time when other programs are barely surviving how do you account for your success?

Answer: I believe that the rate of increase in the President's budget is part of a broader recognition that illicit drug use and drug trafficking continue to constitute major national problems and that in addition to greater efforts to reduce the availability of illicit and dangerous drugs, through law enforement, we must also step up our efforts to understand what drugs actually do to human beings, why it is that they come to be used so compulsively in the face of clearly harmful consequences, how we might prevent or intervene in that process, and finally how we can give better treatment to those who have already become heavily invested in drug use.

We believe that the state of scientific progress holds many opportunitites in each of these areas of research, opportunities that fully justify the proposed dollar increase.

## REDUCTIONS IN STAFF

Question: According to your justification there appear to be some promising breakthroughs in the area of drug abuse prevention. Yet, the budget would reduce staff in the areas of prevention and technical assistance - those who are charged with disseminating this information.

Will this impede you in your responsibilities to get the word out?

Answer: The reduction will be made through administrative efficiencies which should not affect our ability to disseminate information.

## DIETARY GUIDELINES ON ALCOHOL

Question: In February the Department of Agriculture and HHS published proposed new dietary guidelines on alcohol. Current guidelines state that "one to two drinks daily appear to cause no harm in adults". The new guideline states absolutely that no harm is caused and adds that two drinks per day "may actually be beneficial to non-pregnant adults." Doctor, have you seen these guidelines and do you believe it's appropriate for a government agency to, in effect, suggest alcohol is beneficial?

Answer: We have not seen an official copy of the guidelines you refer to. We too have heard of such guidelines through attention they have received in several publications. We would indeed have some concern, based upon the available scientific evidence, about the appropriateness and the accuracy of what we have heard about them.

We anticipate being formally asked to comment on these guidelines. From what I have heard, I question whether the guidelines drop all references to alcohol-related illnesses. We have also heard that there are a variety of recommendations pertinent to alcohol.

## PROBLEMS OF WOMEN WITH ALCOHOL

Question: Reauthorization legislation being considered by the Labor and Human Resources Committee would target additional research funds to investigate the particular problems of women with alcohol. How much of your current effort is targeted toward women and do you believe additional effort is necessary or desirable?

Answer: In FY 1983, the National Institute on Alcohol Abuse and Alcoholism spent almost $1 million for research to investigate the particular problems of women with alcohol. Under the FY 1985 President's Budget, the Institute projects spending $1.3 million.

There has been some progress in the areas of alcohol use, abuse, and consequences which are unique to women but findings are far from conclusive. However, design, methodology, and analytical techniques have become increasingly sophisticated and definitive investigations which focus on alcohol problems peculiar to women have become quite feasible.

An important breakthrough has been in the area of acute effects of alcohol on neuroendocrine hormones essential for reproduction functions in females. Patterns of neuroendocrine hormone secretion during the menstrual cycle in the female rhesus monkey are similar to those in women making this a useful animal model. Recent research results in these animals have paralleled the results of clinical studies in alcoholic women. The replication of behavioral disorders, alcoholism and its pathophysiological consequences in monkeys provides an improved basis for understanding the reproductive disorders associated with alcohol abuse and alcoholism among women.

We do believe that additional research targeted to women is both necessary and desirable. For example, the impact of the changing roles of women in society on drinking behavior remains to be explored. Also, as it has become increasingly apparent that minority and elderly women comprise groups at special risk for alcohol-related health and social problems, research is needed to identify problems of these groups, underlying mechanisms, and to examine innovative studies to develop and test preventive approaches for these populations.

## NIAAA INTRAMURAL PROGRAM

Question: I understand that your new clinical program has been delayed in getting off the ground. Can you tell us the cause of the delay and what the status of the program is currently?

Answer: We are pleased to announce that the National Institute on Alcohol Abuse and Alcoholism's clinical ward is now operational. As in any project of this kind, there had been some delays due to contruction schedules and unanticipated renovation problems. In addition, the NIH Clinical Center has experienced some difficulty in recruiting nurses due to differences in pay and benefits betwen the private sector and those that can be offered by the Clinical Center. However, as of April, 1984, all nurses have now been hired.

## PATIENTS TREATED

Question: How many patients do you expect to treat--both inpatients and outpatients?

Answer: Our ward has the capacity for ten inpatients. We now have an average of seven patients on the ward at any given point, and anticipate that as the routine becomes more established, we can increase the number of patients. We expect that approximately 100 to 130 patients will be involved in inpatient studies each year. In addition, the outpatient program is also operational, and we expect to have approximately 250 to 300 outpatients involved in clinical studies each year.

## NIDA RESEARCH TRAINING

Question: As we increase efforts with respect to research on drugs, why is it that the level of effort with respect to research training remains so low? Indeed, there has been no increase in funds requested for the last two years.

Answer: The number of drug abuse research trainees has declined by about 10% over the past two years in order to accommodate stipend increases and an increasing emphasis on postdoctoral training within a generally level budget amount. Despite this reduction, we continue to receive many more high-quality research applications than the Institute is able to fund; in fact, in 1985 we predict a 21 percent increase in the number of applications received. Furthermore, there is an indication that some scientists are switching to the drug abuse area from other fields of endeavor and thereby relieving our training requirements. While the agency is satisfied with the supply of researchers in the near term, we have begun an in-depth study to review our long term requirements. Should this study demonstrate shortfalls further down the road, we will correspondingly adjust future year budget requests.

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## QUESTIONS SUBMITTED BY SENATOR PETE DOMENICI

## BEHAVIOR REACTIONS TO ENVIRONMENTAL FACTORS

Question. Are there any research funds being allocated to (a) study the efficacy of provocative-neutralizing technique for common foods, pollens and chemicals to mitigate hyperactive and psychotic behavior, (b) study the effects of specific orthomolecular supplements in the treatment of sub-acute clinical schizophrenia and or other behavior diseases, or (c) study the effect of Candida Albicans (a body yeast) sensitivity on human behavior?

Answer. The Institute does not formally allocate funds to study specific treatments such as the ones you describe. The study of specific orthomolecular supplements, however, has been supported when grant applications have met the admittedly rigorous criteria for review. As you know, only a proportion of the applications that are submitted can be supported. Studies of niacin in schizophrenia, pytridoxine in autistic children, and food dyes in hyperactivity are examples of research in this general area that have received support in the past. Further, Institute staff are available to provide consultation to clinical researchers who seek to develop appropriate studies to test specific hypotheses of treatment efficacy.

There has been the suggestion of a potential linkage between Candida Albicans and affective disorder. To date, no applications have been received and there are no data from clinical trials which would shed light on whether there is any relationship at all, and, if so, whether the relationship is one of cause or effect.

Question. Do your research programs reach out to practicing clinicians and are practicing experts included on peer review panels that select and award grants? Here I am referring to orthomolecular biological psychiatrists and clinical ecologists.

Answer. The composition of the NIMH peer review panels attempts to create the highest level of scientific excellence in the substantive area under review. Practicing clinicians/researchers are frequently involved in the review process, particularly in the areas of applied therapeutics, service delivery research, and treatment development and assessment. For example, currently on the Treatment Development and Assessment Committee are two scientists who are involved with dietary factors in mental illness:

Dr. Keith Connors of the Childrens Hospital, Washington, D.C., is a noted child psychopharmacologist who has conducted NIMH-supported research on the effects of food dyes in hyperactive children. He is currently the chairman of the NIMH review committee charged with review of program projects and clinical research centers.

Dr. Alan Gelenberg of Harvard University is a biological psychiatrist who is conducting NIMH-supported research on the treatment of dietary precursors (lecithin and tyrosine) of brain neurotransmitters in mental illness. He currently serves on the review committee charged with review of grants to study biological and somatic treatments for mental illness.

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## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### TREATMENT ASSESSMENT

Question: According to your justification NIAAA awarded a contract last December to develop a multi-faceted study of treatment assessment, outcome and diagnosis. I understand that the contract was let on a sole source basis. In view of the fact that there are many excellent research firms in the Washington area, why wasn't this contract let on a competitive bid basis?

Answer: The contract in question was awarded to Metrotec, Inc., under the provisions of the 8(a) set-aside program of the Small Business Administration (SBA). Under Federal Procurement

Regulations (1-1.713.2), it is the policy of the Executive Branch of the Government to increase the participation of economically and socially disadvantaged small business firms in Government procurement by awarding to such firms contracts through the "8(a) program." This program is authorized under Section 8(a) of the Small Business Act and is implemented by awarding a prime contract to the SBA which then awards a subcontract to an eligible 8(a) firm. Nominations of 8(a) firms to be awarded the subcontract are submitted to SBA by the initiating agency. The SBA has the sole responsibility for determining the eligibility of firms to participate in this program.

A negotiation between SBA and the Secretary of the Department of Health and Human Services establishes goals to award a specific percentage of the Department's total procurement budget to eligible firms under the 8(a) program. As a first priority, therefore, an agency must assess each procurement to determine if it can be awarded to an 8(a) firm. If it cannot be awarded under the 8(a) program, other set-aside programs must be considered (for example, small business or labor surplus) before the procurement may be permitted to be awarded on a fully competitive basis.

Under the 8(a) program, awards can be made on a sole source basis or competed among 8(a) firms. When one 8(a) firm has predominant capability by reason of experience, specialized facilities or technical competence to perform the project, an 8(a) award may be made sole source. In this instance, Metrotec had extensive experience in producing documents similar in content and format to those required in the National Institute on Alcohol Abuse and Alcoholism's procurement, and Metrotec's performance on such contracts had been noted on prior projects as being exemplary. Therefore, a recommendation was made and approved for the award of this project on a sole source basis to Metrotec under the 8(a) program.

## ALCOHOLISM SERVICES DEMONSTRATION PROJECT

Question: I understand that NIAAA is engaged with HCFA in a joint alcoholism services demonstration project involving seven States, 120 providers and 5,200 patients in the first year. NIAAA is providing administrative and evaluative services. Could you give us a progress report?

Answer: In FY 1981, the Health Care Financing Administration and the National Institute on Alcohol Abuse and Alcoholism jointly began a demonstration program, including an independent evaluation component, designed to test the feasibility and effectiveness of providing alcoholism treatment to Medicare beneficiaries and Medicaid recipients in less costly settings such as free-standing residential and outpatient facilities and halfway houses. The effectiveness of utilizing personnel other than physicians, i.e., alcoholism counselors, in the treatment of alcoholism is also being tested. This demonstration has been paying for services in lower cost alternatives to hospitals since July 1, 1982. Presently, there are 159 service settings for detoxification, inpatient treatment or outpatient treatment. Ninety-eight participating alcoholism treatment programs are providing these services in areas within the six participating States of Connecticut, Illinois, Michigan, New Jersey, New York, and Oklahoma.

The demonstration will gather data through December 31, 1985. The comprehensive evaluation of the demonstration is expected to be completed by December 31, 1986. It is premature to comment on the preliminary findings. When all the data has been collected and evaluated, the results of the 4-year demonstration will be published and forwarded to the Congress by the Department.

Question: Why couldn't this study be utilized to explore the parameters of a standardized patient placement system?

Answer: The primary purpose of the Medicare/Medicaid alcoholism treatment services demonstration is to gather utilization and cost data essential to informed deliberations about extensions of Medicare and Medicaid services to lower cost alternative settings.

Some of the data expected from the evaluation of this demonstration may provide detailed information on client characteristics, treatment activities and outcomes. However, the eligible populations are limited to about 20% of the nation's population -- the aged, disabled and the medically indigent, and thus the data would need to be considered with details from other populations in both hospital and alternative settings in order to have enough information for a standardized patient placement model. Another limitation in the use of the evaluation data for a standardized patient placement system is that behavioral outcome measures will be based on 1-year post-treatment followup rather than the longer term followup (e.g. 3-5 years) needed for a comprehensive patient placement model.

## DRUG ABUSE RESEARCH PRIORITIES

Question: In what priority areas will you concentrate your efforts?

Answer: Mr. Proxmire, our efforts in FY 1985 will range from some very basic research on how drugs act on the brain to applied research on how to increase the effectiveness of our prevention and treatment programs. In brief, our efforts will concentrate on five major areas.

### BASIC RESEARCH

First, we will expand our neurosciences program. Recent breakthroughs in the neurosciences are greatly accelerating the pace of research in this field and providing the possibility of extremely important, clinically significant findings in the near future.

For example, recent work indicates that the reason narcotics, and several other drugs, produce such strong dependence is that they activate what may be a basic reward mechanism within the brain. Specific areas of the brain have been identified, the ventral tegmental area and the nucleus accumbens, involving neurons in which the neurotransmitter dopamine appears to play a crucial role in the rewarding effects produced by food and water. Micro injections of morphine in this area in animals are rewarding, i.e., animals will work for them by pressing levers, while injections into other areas, though they do produce other typically opiate-like effects, are not. Micro injections of opiate antagonists, chemicals which block the effects of opiates, into this region tend, at low doses, to make animals increase their efforts to obtain intravenous morphine - as though to compensate for the effect of the antagonist - and, at high doses, to stop the animals efforts for intravenous morphine. It appears, therefore, that the rewarding effects of narcotics are due, at least in part, to their action on this particular part of the brain.

The results of this research may revolutionize our understanding of how the brain works. It may also lead to significant advances in the development of new chemical ways of treating drug abuse. For example, if a way could be found to block the effects of drugs on particular portions of the brain through the development of suitable antagonists without interfering its normal functioning, it might be possible to block the euphoric effects of a wide variety of abused drugs with a single substance in much the same way that we can now block the effects of narcotics with drugs such as naltrexone or buprenorphine.

## CONSEQUENCES OF DRUG USE

A second important area which will be expanded is research on the health and behavioral consequences of drug use. Most of our current efforts have been directed at the health effects of chronic drug use. For example, we are looking at the effects of long-term drug use on heart and pulmonary function, brain development, reproductive functioning, and on the immune system.

Recently, however, we have begun to place more emphasis on the more immediate effects of drug use and also to focus on particularly on chronic behavioral and central nervous system effects. There are two areas of special concern. First, while drug abuse has a long history in the United States, the degree to which drug abuse now involves the young is unprecedented. This is a problem of special concern because adolescence is a period of exceptionally important and rapid psychological and physical development and, even without the influence of drugs, a time of exceptional turbulence. We are, therefore, particularly concerned to find out what the effects of frequent drug use by adolescents is on their emotional, intellectual, and physical development.

Second, we are expanding our research to determine what the effects of drug use are on complex psychomotor performance. We live in a society that makes tremendous demands on our abilities to safely perform many complex activities, from driving automobiles to operating sophisticated electronic and mechanical machinery. We do not understand well, at all, what the effects of recent, but not current, drug intoxication may be on these abilities. What, for example, is the effect of drug use on a weekend on these abilities over the course of the next week or month? This is an area of extreme importance and will be the focus of much of our upcoming efforts.

## DRUG ABUSE TREATMENT RESEARCH

The third major area that will be expanded will be in research on the treatment of drug abuse. Three areas will receive special attention. First, one of the major problems with most current pharmaceutical treatment agents for narcotic addiction is that they must be taken frequently. To correct this, the institute is working in two areas; to develop longer acting treatment agents and to develop new drug delivery systems which would eliminate the need for "drug taking" behavior. For example, the possibility of maintaining a sufficient blood concentration of naltrexone to block a dose of morphine over several weeks has been established. During the next two years a more conveniently administered delivery system, a form of implant under the skin, will be clinically tested. Second, many studies have shown that narcotic addicts also suffer from various psychological problems and that the addition of psychotherapy or counseling to drug abuse treatment programs can make them more effective. One of the problems in providing such treatment services is to determine which of many possible combinations of treatment regimens would be most effective for a given individual. Research to develop diagnostic tools to facilitate this effort is a high priority and may greatly increase the success rates of treatment. Finally, the large numbers of young drug abusers currently seeking treatment for non-opiate drug problems has caused us to expand our research on the effectiveness of treatment programs directed specifically at this population.

## PREVENTION RESEARCH

The fourth area that will be expanded is prevention research. Our prevention research program has two major goals; the evaluation of the effectiveness of prevention programs, and the identification of risk factors associated with drug abuse. The overriding goal of both of these efforts is to make our prevention programs more cost effective. The evaluation program will continue to study new and innovative prevention programs throughout the country. Recently, the success of several prevention programs has been demonstrated under tightly controlled circumstances. One of our major efforts in the future will be to evaluate the success of these programs under a wider variety of more natural conditions. Particular importance will be given to testing community-wide prevention programs. The efforts to identify risk factors associated with drug abuse will complement the evaluation program. It is well known that not everyone given the opportunity to try drugs does, and only a small portion of those who try them go on to compulsive use. There are also significant differences in drug use patterns among various ethnic groups. If we could identify factors that are associated with an increased likelihood of progression from no use to regular use, we could greatly increase the effectiveness of our prevention programs by directing them specifically at high risk groups. The expansion of research in this area, which is currently in its early stages in the drug abuse field, is a high priority for FY 1985.

## EPIDEMIOLOGY RESEARCH

The final area that will be expanded is research on the epidemiology of drug abuse. At the current time we have excellent epidemiological information in two areas: on the consequences of drug abuse and on drug use in household members. There are two areas where we do not have adequate information: first, drug use by high risk groups outside of households, for example, college students, people in the military, and single people who move frequently. The second is information on people in treatment for drug abuse. We no longer have reliable information on either the numbers of people in treatment for drug abuse, the specific problems for which they are being treated, or the range of services being provided. The collection of accurate information in these two areas is important both for the development of public health policy and the direction of our research program.

## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### HEALTH AND BEHAVIOR

Question: The Committee understands that pursuant to its recommendation last year, that the leadership of the National Institute of Health and the National Institute of Mental Health has agreed to request an additional $7 million this year in order to jointly implement various preventive/behavioral health recommendations following up on HEALTHY PEOPLE and the Institute of Medicine report, HEALTH AND BEHAVIOR. The Committee further understands that the Office of Management and Budget specifically deleted these funds. Accordingly, the Committee would like to learn if this is in fact the case, and further, if so, whether the Department has any plans for following up in this area within its present budget request.

Answer: Due to the current economic conditions and the need to reduce overall Federal spending, a new initiative on Health and Behavior was not included in the President's budget. Nevertheless, a PHS Working Group on Health and Behavior has been formed to foster collaborative research activities in this area. We are already making a substantial commitment to research on health and behavior in NIMH and NIH with currently available budgetary resources.

## SAINT ELIZABETHS HOSPITAL

### STATEMENT OF LARRY B. SILVER, ACTING DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

ACCOMPANIED BY:
- WILLIAM G. PRESCOTT, SUPERINTENDENT, SAINT ELIZABETHS HOSPITAL
- ANTHONY L. ITTEILAG, DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

### PREPARED STATEMENT

Senator EAGLETON. We will now hear from Dr. Silver on Saint Elizabeths.

Dr. SILVER. Senator, if I may, I would like to summarize my statement and submit for the record the formal one.

[The statement follows:]

## STATEMENT OF LARRY B. SILVER

Thank you for the opportunity to present the programs of Saint Elizabeths Hospital. As the first order of business, I would like to note that on January 1, Dr. William G. Prescott was appointed Superintendent of the Hospital. Dr. Prescott is a psychiatrist and a U.S. Public Health Service Officer. Formerly, he was Director of the Cuban/Haitian Mental Health Unit at NIMH. He has a unique combination of professional experience and managerial skill, which makes us feel very comfortable about the future leadership of the Hospital.

The past year has been both eventful and difficult for Saint Elizabeths. In a relatively compressed period of time, there has been: a substantial reduction in staff and operating costs; a fundamental realignment of the management structure; an overhaul of the fiscal and accounting system; and the initiation of a variety of efforts designed to relocate inappropriately placed patients to more suitable facilities. All of these events have been directed toward the goal of producing an effective, efficient and self-sustaining facility which will be responsive to the needs of the community it serves. The Federal role will, at that time, consist of support of care for Federal beneficiaries remaining at the Hospital, as well as payment for the use of staff and a clinical base for the continuation of NIMH intramural research. None of these things would have been possible without the cooperation of the Hospital staff, the Congress, and the District of Columbia.

### Patient Care

It is important to focus first on the patients, since management changes are of value only to the extent that they help the clients they serve. There are two distinct tasks: first, to enable those who are mentally ill to receive the best treatment available; and second, to ensure that those persons whose primary need is for long-term care, or treatment for substance abuse, will have access to the most appropriate and affordable facilities.

We were especially mindful of the needs of those persons with a primary diagnosis of mental illness during the recent period of reorganization and staff reductions. The cost savings, along with consolidation of programs and modest staff reductions, were accomplished with minimal disruption. Moreover, the ratio of staff to inpatients remains virtually the same as that in effect when the Hospital was surveyed in 1981 by the Joint Commission on Accreditation of Hospitals.

For those patients who inappropriately reside at Saint Elizabeths, the District has agreed to place 200 additional hospital inpatients who require custodial care in nursing homes or community residential facilities. The District government also agreed to accept responsibility for the care and treatment of patients now admitted to the hospital's Community Mental Health Center alcohol and drug abuse treatment programs. These events permit us to project an average daily inpatient population of 1,374 in 1984, a 16 percent decrease from 1983.

## Accreditation

Although accreditation is not an end in itself, it is a valid indicator of the quality of patient care. The Hospital is currently fully accredited by the Joint Commission on Accreditation of Hospitals (JCAH), and we feel comfortable that this accreditation will be renewed later this year. I might mention that the Area D Community Mental Health Center was separately surveyed last October, and received its own individual certification, which is good for three years. To assure that there will be no unforeseen problems related to the recent staffing changes, the JCAH was notified of our actions. In addition to the JCAH certification, the Hospital has just been surveyed for continued eligibility as a Medicare and Medicaid service provider. We are awaiting results of that survey.

## Management Improvements

In an effort to contain operating costs, we are examining several hospital activities as required by OMB Circular A-76, to determine whether it is more efficient and cost effective to continue to perform them with in-house staff or handle them through contracts. Ultimately, some 34 activities will be examined. At present, the laundry, housekeeping and dietary functions are being studied.

The hospital is also implementing an automated billing system to assist in generating and tracking revenues for patient care. This system becomes increasingly important, since we are expanding our revenue base among a variety of Federal agencies, Medicare, Medicaid, commercial insurance carriers, and patients who have the ability to make a fair contribution to the cost of their care.

The Hospital is also in the process of consolidating two of its adult psychiatric divisions and a number of its smaller specialty treatment programs.

## Future of the Hospital

This year, we will be submitting legislation to establish the Hospital as a private, non-profit corporation. The budget request, although constructed within the framework of the present authorizing legislation, will be fully compatible with the new corporate structure. During a ten year period - with 1985 being the third year - the Federal subsidy to the Hospital will gradually decrease to zero. At the end of this transitional period, the District of Columbia will pay the full cost of care for its patients, and Federal funds will consist only of Medicare and Medicaid payments, support for those Federal beneficiaries still cared for by the corporation, and support for NIMH intramural research.

Recently, the District of Columbia and the General Accounting Office have presented their own recommendations for combining the hospital with the District's mental health system. All three proposals concur in the most basic elements, which include:

- Full integration with local mental health programs;
- A transition period at the end of which the District of Columbia assumes greater financial responsibility; and
- Careful attention to the issue of placement of patients in the most appropriate care programs.

With agreement on these three basic points, we feel that the prospects for reaching a workable and responsible solution are most encouraging. There are still some differences to be worked out, however. The other two proposals envision direct organizational control of the Hospital by the District, as opposed to the corporate model which we propose. The District's plan assumes a somewhat longer transition period than that of the GAO, and would not fully utilize the existing physical plant.

## Budget Request

The total 1985 budget request is $126,743,000, representing a decrease of $2,990,000 below the 1984 level. The net decrease results from a combination of several factors which include increases of $6,868,000 for mandatory items and $2,500,000 for improvement of the telephone system, offset by a decrease of $12,358,000 representing annualized savings from the staff reductions effected last year, nonrecurring termination expense costs, and other management improvements.

Within the total budget, the direct HHS appropriation request in 1985 is $48,595,000. This represents a decrease of $21,231,000 below the level of appropriated and transferred funds anticipated in 1984. The decrease in appropriations reflects all of the factors I just described for the total budget, plus an increase of $19 million in the District of Columbia's reimbursed share of the cost of care for its residents.

### INTRODUCTION OF ASSOCIATE

Dr. SILVER. I am very pleased to introduced Dr. William Prescott, the new Superintendent of Saint Elizabeths Hospital, who began in January.

The past year has been a very difficult year for Saint Elizabeths Hospital. We had a reduction in budget which required us to undertake a reduction in force, and had to undertake some very careful management studies and some management efficiency efforts. We are very pleased that we were able to go through that without negatively impacting on clinical care or accreditation.

### REDUCTION IN PATIENT LOAD

The census in the hospital has begun to decrease because of some cooperative work with the District of Columbia. We have been able to start a process of out-placing up to 200 individuals who need the type of care provided by nursing homes and 50 people who need a more special type of community program; 89 individuals in an alcohol and drug program that had been run for District residents has been picked up by the District. This combines to a 16-percent reduction in patient load.

Senator EAGLETON. In 1 year it is down 16 percent?

### MANAGEMENT IMPROVEMENTS

Dr. SILVER. Yes, sir, during this fiscal year.

We are also pleased that the Joint Commission on Accreditation of Hospitals approved the hospital in 1981. The hospital is due for reassessment at the end of this calendar year, and we feel that it should be able to address the issues necessary for further accreditation.

The joint commission also looked at our Community Mental Health Center in October 1983 and approved it in terms of meeting their qualifications.

A report on medicare and medicaid recently came out in February; and, although we don't have a copy of the formal report yet, the summary suggested that we were in a good position to qualify for these programs, too.

We have also been going through the required A–76 reviews, starting with housekeeping, food service, and laundry; and are now almost ready to complete that process. We will soon be starting reviews in other areas.

In terms of the future of the hospital, I am delighted with the quality of the staff and with the leadership that Dr. Prescott has brought, and we feel that we can continue to operate the hospital at a level of quality.

### POTENTIAL DEFICIT IN 1985

Our one concern, and the one that will be the issue for this committee and for the House Appropriations Committee, is that at the moment, as best we understand the District budget, there will be a $19 million shortfall this year between the Federal budget and District budget in the amount of money needed to operate the hospital. Last year, as you will recall, there was a $25 million shortfall and we absorbed that through some management efficiencies, by dealing with nonpatient care areas, and by some negotiating with the District in terms of their picking up certain patients. My concern is that if this $19 million shortfall exists this year, there is absolutely no way we could absorb that much of a cut without moving into clinical care and perhaps jeopardizing our accreditation.

At this point I will be happy to answer any questions.

Senator EAGLETON. I would suspect you are right. Last year you had to really do a yeoman job to get the $25 million. To squeeze another $19 million is virtually impossible. What are we going to do? Where is the give?

Dr. SILVER. We believe that the critical issue of funding must be resolved by Congress, since different committees have responsibility for the hospital and the District of Columbia. We sincerely hope that Congress will take the lead in working on that because we may end up with a shortfall again unless the District Appropriations Committee and this Appropriations Committee work together.

Senator EAGLETON. I would like to write a letter just to flag this issue to Senator D'Amato and whoever the ranking Democrat is on that committee and circulate it around. If you could give me a modest sized paper on what the consequences would be of a $19 million cut in terms of real loss of clinical services—I'm talking about two pages, not an anthology—I would very much like to have it, and I will try to run it between committees. What can sometimes happen is it can fall between the cracks. This committee can say, no, that's the DC committee's stuff, or the DC committee can say, no, that ought to be over there in HHS.

Dr. SILVER. We will do that. We appreciate that, because we feel it will be disastrous if it doesn't get worked out.

[The information follows:]

### SAINT ELIZABETHS HOSPITAL IMPACT OF $19.8 MILLION FUNDING SHORTFALL IN FISCAL YEAR 1985

To assess the impact of a $19.8 million shortfall in 1985, it is first necessary to describe the effects of steps already taken in order to accommodate budget reductions made this year. The present (fiscal year 1984) hospital budget reflects a $14 million cutback in operating costs. The cutback was effected as part of several efforts to cope with what was originally a projected $25 million shortfall for the current year. The shortfall was averted through a commitment by the District of Columbia to accept responsibility for 289 patients (resulting in savings of $5.3 million), a $5.7 million increase in the Federal payment to the District of Columbia which was earmarked for Saint Elizabeths Hospital, and $14 million in management savings.

In order to achieve a $14 million savings in 1984, expenditures for supplies, equipment, and contractual services were reduced to the lowest level consistent with continued hospital operations. However, most of the reduction still had to be achieved through a reduction in force. In December 1983, a total of 216 employees were given separation notices, and 116 other elected early retirement. Despite the loss of staff, but only after a major effort, it was possible to maintain a ratio of clinical staff to patients which was comparable to that which existed at the time the hospital regained its accreditation approximately 5 years ago. However, there is no margin left for contingencies.

When added to the events previously described, a $19.8 million reduction in the hospital's budget next year would fundamentally affect its ability to provide clinical care. It would result in loss of accreditation, and would impede the capacity of the hospital to obtain reimbursements for services—even at the lower projected income level.

The hospital would have no choice but to achieve the bulk of the savings through further reductions in force, since nearly 80 percent of the budget is required for salary costs. Not more than $4 million of the $19.8 million total could be recovered in nonsalary areas directly associated with the position reduction, including supplies, equipment, and contractual services. Any further reductions in the nonsalary area would jeopardize the most basic patient support needs such as food, medicines, and the contractual provision of medical and surgical care.

In order to save the remaining $15.8 million in salary costs, it would be necessary for the hospital to reduce its employment by an equivalent of 495 full-time positions. This would represent 14 percent of predicted 1985 employment, and would constitute a reduction of 23 percent below the staffing levels of 1 year ago. Because a staffing cut of this magnitude could only be achieved through a reduction in force [RIF], the RIF itself would generate termination expenses of between $3 and $4 million. In the absence of additional appropriations, these termination expenses (lump sum leave payments, unemployment compensation, and severance pay) would necessitate still further staff reductions in order to generate the necessary additional savings to pay them. In total, the combination of lost revenue and unbudgeted RIF costs could result in a net loss of nearly 615 full-time equivalent positions in 1985.

An additional issue of concern is the effect of a further loss of resources upon the ability of the hospital to bill for, and recover, revenues. The hospital is currently embarking on a 2-year effort to upgrade its billing and collection system in order to assure that it meets all requirements of the public and private health insurance industries. Whether undertaken through contract or with in-house staff, this is a multimillion dollar effort which must be completed if the hospital expects to develop a permanent and acceptable mechanism for generating revenue. The hospital currently bases its bills on a flat per diem charge—a method which most of its payors have accepted only on a temporary basis. If the conversion process must be deferred due to lack of staff or funds, there will likely be a further loss of revenue beyond the projected $19.8 million shortfall.

In 1985, the hospital cannot achieve further savings without threatening accreditation. At a minimum, severe cuts in several important patient care areas will be necessary should a $19.8 million shortfall occur including medical, outpatient, child and adolescent, and general adult inpatient services. In addition, a shortfall will trigger a further loss of reimbursements from public and private payors because the hospital will fail to meet quality of care requirements.

In summary, there would be two immediate effects of a $19.8 million revenue loss in 1985: a downgrading of the quality of inpatient treatment with resulting increases in the average length of stay; and a succession of secondary revenue losses, precipitated by a disruption of the hospital's basic earning capacity.

### ST. ELIZABETHS 10-YEAR PLAN

Senator EAGLETON. It makes no difference to me out of which pocket it comes to get the $19 million, just so the job can be done, and where it belongs in terms of tidy bookkeeping I'll let somebody else argue about. But it shouldn't be left in the middle in no man's land.

You and I had an exchange a few months ago on Saint Elizabeths about the 5-year plan, right?

Dr. SILVER. Ten-year plan.

Senator EAGLETON. Is the administration's position with respect to that plan pretty much the same now as it was back then?

Dr. SILVER. Yes, sir; the feeling is that each year the Federal Government's involvement decreases the District involvement increases.

### SEH SUPERINTENDENT

Senator EAGLETON. Dr. Prescott, tell us about yourself. You say you came in January?

Dr. PRESCOTT. Yes, sir.

Senator EAGLETON. From whence did you spring?

Dr. PRESCOTT. Prior to that, sir, I was the Director of the Cuban-Haitian Mental Health Unit, which is a small part of NIMH especially designed to treat the mental health needs of the Cubans and Haitians that came in 1980 in the Mariel boatlift. Prior to that I was chief of psychiatry at the Public Health Service hospital in San Francisco, CA.

### STAFF AT HOSPITAL

Senator EAGLETON. So you are not a total stranger to Saint Elizabeths. Had you ever served there in staff capacity or training capacity?

Dr. PRESCOTT. No, sir; I hadn't.

Senator EAGLETON. How big is the full-time medical staff, M.D.'s at Saint Elizabeths?

Dr. PRESCOTT. We have about 137 psychiatrists there and around 50 general medical officers or people who serve in a general medical function. Some are actually internists and one is a board certified surgeon.

Senator EAGLETON. And those basically are full-time?

Dr. PRESCOTT. Yes; we have 74 psychologists as well.

Senator EAGLETON. Are there half-time people or quarter-time people?

Dr. PRESCOTT. Yes; there are a number of people also on appointments that are other than full-time.

### RELATION OF EMPLOYMENT TO PATIENTS

Senator EAGLETON. You heard Dr. Silver mention that the patient load is down 16 percent. This is for the past calendar year or fiscal year?

Dr. SILVER. It is in the process of fiscal year 1984 that the District is picking up the additional patients.

Senator EAGLETON. If you know, Dr. Prescott, and if you don't, maybe Dr. Silver does, has there been any reduction in the professional staff?

Dr. SILVER. As part of the reduction in force we went through in December 1983 we took into account this reduction in patient population. In order to maintain some staff until this transition took place we appointed some people to temporary or term appointments which will be expiring at different periods over this year. Our staffing pattern, however, will reflect the reduction in patients.

Senator EAGLETON. Thus it could be pretty much in lock step? If patients are down 16 percent staff is going to be down, give or take, in that range?

Dr. SILVER. It won't be that even, because so many of the core services that we have to provide at Saint Elizabeths Hospital, such as housekeeping, buildings and grounds, security, will have to stay the same for the same patient load, but the ratio of professional staff to patients should reflect the changes.

Senator EAGLETON. Is it hard to recruit psychiatrists, internists, or psychologists for Saint Elizabeths?

Dr. PRESCOTT. So far the recruitment of psychiatrists has not been a major problem. There are some problems recruiting other areas of professional staff, such as nurses, but we are taking steps to address those needs at the moment. Psychiatrists have not been a major problem at this point.

Senator EAGLETON. What is a nurse at Saint Elizabeths paid?

Dr. PRESCOTT. They are, I believe, general schedules 7 to 11 depending on prior service, training, and qualifications.

Senator EAGLETON. What is that in dollars, roughly?

Dr. PRESCOTT. Seventeen to twenty-five thousand dollars per year.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator EAGLETON. I want to thank you, Dr. Silver and Dr. Prescott. We do have these questions in writing for the whole team that was here.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Question: Once again the budget request assumes that the D.C. Government will assume a larger proportion of the operating expenses of St. Elizabeths.

What is the amount of the increased share you expect to be picked up by D.C.?

Answer: We expect the District's share to be $54,959,000 in 1985, or $19,000,000 more than this year's level.

Question: Has the D.C. Government budgeted for this increase?

Answer: We have not received official information on the content of the D.C. budget, as the District submits its estimates approximately 3 months after the executive agencies. However, although the District is aware of the increase, we have been informally advised that the Mayor's 1985 budget request does not include the projected increase.

### POTENTIAL BUDGET SHORTFALL

Question: Last year you had to make several millions of dollars of management savings in order to offset the deficit between Federal and D.C. appropriations. In the event funds are not forthcoming to alleviate the shortfall, is there any fat left in the Hospital?

Answer: In the event a further deficit arises in FY 1985, the Hospital would have to make programmatic changes which will result in limitations on current patient services. There are no areas in the Hospital that have excess resources. The only remaining discretionary item in the 1985 budget is a $2.5 million increase for the telephone system requisition. The Hospital would have to accelerate the process of review of commercial and industrial activities pursuant to OMB Circular A-76 in an effort to identify any possible areas where further savings can be accomplished. However, having acted in those areas where it was known that savings might occur already, it is not likely that major savings can be achieved via the A-76 process in FY 1985.

### SERVICE REDUCTION

Question: What kinds of services to patients will be affected, and at what point does the Hospital's accreditation become endangered?

Answer: If another deficit arises in FY 1985 at the currently identified level of $19.8 million, services to patients are most likely to be affected in the areas of: (1) medical services, (2) outpatient services, (3) child and adolescent services, and (4) adult psychiatry, by virtue of reductions in the number of staff servicing inpatients but not the total elimination of services. Reductions of any amount will endanger the Hospital's accreditation, since the FY 1984 budget cuts eliminated any margin of safety. Such a survey is currently scheduled for the later part of calendar 1984.

## DELAY IN OUTPLACEMENT

Question: As part of the agreement late last year to solve the funding problems of the Hospital, the D.C. Government agreed to assume responsibility for some 289 patients early in FY 1984. It is my understanding that this transfer has not been completed and has resulted in $300,000 in unbudgeted cost to the Hospital.

What is the reason for the delay and how will you pay the additional costs of care for these individuals?

Answer: The District government has made a good faith effort to assume responsibility for 289 patients as agreed at the beginning of the Fiscal Year. Last year the District of Columbia agreed to accept responsibility for 150 patients requiring nursing care (in addition to the ususal rate of 50 nursing home outplacements during a six-month period), 50 patients requiring community residential care, and 89 patients in the alcohol and drug abuse program. As a result of the District's efforts, 113 patients have been transferred to nursing homes since the beginning of the year. None of the 50 patients requiring community residential care has yet been transferred. The District has recently signed a contract with a private provider to deliver alcohol and drug abuse treatment and has assumed responsibility for the patients previously served in the Area D alcohol and drug treatment program. Apparently, the magnitude of the task was somewhat underestimated, particularly in the area of achieving placements for patients who require special services.

The final FY 1984 budget included $5 million recommended by the Senate Labor, and Health and Human Services Appropriation Subcommittee for transition expenses associated with the budget cuts. These funds are being used not only for severance pay and other reduction-in-force related expenses, but also for salaries of temporary employees retained for the purposes of providing care to patients awaiting transfer to District Government responsibility.

## FUTURE PLANS FOR HOSPITAL

Question: The Administration, GAO, and the D.C. Government have all come forward with plans for D.C. to assume a greater share of responsibility for the Hospital's management and funding. Can you briefy describe the differences in the three plans and tell us if the Department is absolutely locked in to the corporation approach?

Answer: We are providing, for the record, a statement which summarizes the three plans. We believe that the Corporation approach is the best available alternative. To that end, we have submitted the necessary authorizing legislation to the Congress. However, we are still prepared to consider any other proposal which would provide the essential similar features, including a continued phasing-down of Federal support, an integrated mental health system, and local responsibility for that system.

## PROPOSALS FOR THE FUTURE OF SAINT ELIZABETHS HOSPITAL

The three current proposals for the future of Saint Elizabeths Hospital are similar in several important respects. All call for a single mental health service delivery system for the District of Columbia with administration of that system under local control and with the bulk of the funding being a local responsibility. Some of the units currently part of SEH would continue to be national and Federally financed--training, research, and the mental health program for the deaf. Outplacement of all possible patients to nursing homes and community residential facilities with necessary psychiatric services being provided by community mental health centers would occur under all three proposals. The present forensic facility at SEH would continue to be used for that purpose in all proposals. None of the proposals address capital costs. Important differences in the three are noted below.

### Administration's Corporation Proposal

The proposed private non-profit corporation would provide all mental health services for the District of Columbia. The corporation would be responsible for existing staff, facilities, and patients of both SEH and D.C. Mental Health Services Administration. The board of directors would, after an initial transition, have practically all of its members appointed by the Mayor. Although the board might make changes, it is assumed that the services currently provided by SEH would continue. Federal payments, except for specified classes of patients, research, training and Medicaid Federal financial participation and Medicare would decline to zero after FY 1992. Currently available cost estimates, for the hospital alone and not the entire corporation, call for a FY 1985 budget of $126.8 million increasing, because of inflation, to $144.0 million in FY 1992. The Federal subsidy proposed for the hospital would decline from $48.6 million to $11.4 million in 1992, and phase out competely in 1993.

### District of Columbia Proposal

At present, the Mayor of the District of Columbia has made a general proposal, based on a consultant's report (Pickman Report) which is much more specific. All details of the D.C. proposal are not yet final and are subject to change by a commission which the Mayor has established entitled the "Ad Hoc Advisory Commission on Mental Health Services Reorganization" which began work in mid-March. In general, this proposal is broader in scope than the other two and includes delivery of certain social services as well as mental health services. Except for continued Federal research and training activities, Federal beneficiaries, a group of approximately 400 chronic elderly patients, and the Forensic facility (and perhaps the Area D CMHC facility), the proposal does not recommend the continuation of Saint Elizabeths Hospital as presently constituted. Movement of programs from SEH to alternative facilities would begin in FY 1985 and be completed in six years. Services for acute psychiatric patients would be transferred to general hospitals in the District; all childrens' services would be moved and 200 chronic inpatients would be relocated. All present SEH employees would be the responsibility of the Federal government as would the current SEH physical facility. Costs, calculated by the District without any inflation factor, for the programs that would remain at SEH, are estimated to decline to $39 million by 1990 from the $126.8 million level of FY 1984. The Federal share of that amount would be $27 million in 1990 and the District would contribute nothing. The consultant's report anticipates minimal or no cost reductions in the system as a whole from either out-placements or shifting of acute psychiatric care. The Federal subsidy would remain at approximately the 1984 level during the 6 year transition period, except to the extent that overall hospital costs would decline. After the transition period, the Mayor's preliminary proposal calls for the Federal Government to pay a permanent fiscal entitlement to the District of about $40 million in support of the mental health system in addition to the costs of the specific Federal program responsibilities.

## General Accounting Office Proposal

The GAO proposal, which at this date has only been circulated in a draft report and is subject to change before final presentation to the Congress, deals only with the transfer of SEH to the District of Columbia. The GAO estimates that the Hospital can decline to a total size of approximately 1,000 beds by outplacement of appropriate patients and by moving all acute psychiatric care. The GAO calls for a two year transition to begin in FY 1986. Although the plan calls for a significant reduction in the number of staff at SEH, it does not deal with positions and suggests that special action by the Congress will be required to address that question. Using FY 1983 as its base year the GAO estimates that $22 million in annual operating costs could be saved if staffing patterns were shifted to the "Ohio Model" and if approximately 700 SEH patients were moved to more appropriate and less costly facilities. After the transition period is completed and using the GAO calculations based on FY 1983 with no inflation adjustments, the system as a whole is estimated to cost $121.9 million with the Federal portion being $40.2 million. For the Hospital alone (excluding research, training, and the deaf program), the cost estimate is $60.75 million with the Federal share being $14.0 million. The GAO recommends that during the two year transition the Federal government pay a direct subsidy of $40 million a year.

## SEH EMPLOYEES

Question: What is the Department's position with respect to the status of St. Elizabeths' employees?

Answer: Matters concerning adequate and competent staffing of the hospital under the Corporation proposal and the interests of SEH personnel have been given particular attention. The principles for personnel provisions of the corporation bill focused on three major objectives with respect to the status of St. Elizabeths'. Employees would be transferred to the new corporation; employees would be protected to the maximum; and the corporation should have considerable flexibility with regard to authority over the employees within the principles of a merit system.

Question: They are currently Federal employees. Would they be transferred to D.C.?

Answer: The legislation submitted to Congress proposes a non-profit private corporation to provide mental health services for the District of Columbia. As such, employees would neither be Federal nor District government employees. As noted earlier, the corporation will be setting up its own personnel system. Protective measures are included for employees who are transferred to the corporation. At the time the corporation is created employees of both the District and the Federal government will be transferred with no reduction in salary. The transferred employees will have the option to continue in the Federal retirement system and Life Insurance programs as long as they wish. Transferred employees will continue to participate in the Federal Workman's Compensation and health benefit programs for a three year period. Accrued annual and sick leave will also be transferred with their accounts and any employee terminated through reduction in force, subsequent to the formation of the corporation, will be entitled to severance pay equal to that of a Federal employee.

Question: Also, do you have an estimate of the number of employees necessary to run the hospital once a transfer is effected?

Answer: Initially, we would expect the staff to remain at approximately the same level as in 1984, which includes 3,385 full-time permanent positions and the full time equivalent of 92 other than-permanent positions. However, this number could decline in 1985 or 1986, to the extent that the hospital is able to contract out certain of its support services and the District is able to outplace further patients.

## SUBCOMMITTEE RECESS

Senator EAGLETON. The subcommittee will stand in recess until Tuesday, April 10, at 9 a.m. in SD–116, Dirksen, when we will hear from health and human services witnesses for the Office of Inspector General, Office for Civil Rights, policy research, departmental management, salaries and expenses.

[Whereupon at 12:15 p.m., Thursday, April 5, the subcommittee was recessed, to reconvene at 9 a.m., Tuesday, April 10.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1985

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TUESDAY, APRIL 10, 1984

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9 a.m., in Room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### DEPARTMENTAL MANAGEMENT

### STATEMENT OF HON. JOHN J. O'SHAUGHNESSY, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

ACCOMPANIED BY:
- DR. ROBERT RUBIN, ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
- RICHARD KUSSEROW, INSPECTOR GENERAL
- JOHN HOPKINS, DIRECTOR, OFFICE OF THE SECRETARY, BUDGET SERVICES
- ANTHONY ITTEILAG, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

### PREPARED STATEMENT

Senator WEICKER. The subcommittee will come to order.

We are holding our final day of hearings on the fiscal year 1985 request for the Department of Health and Human Services.

John O'Shaughnessy, Assistant Secretary for Management and Budget, will be our principal witness and will summarize for us four sections of the departmental management appropriations: General departmental management, the Office for Civil Rights, the Office of the Inspector General, and policy research.

Mr. O'Shaughnessy, if you'll introduce your colleagues and proceed with your summary, your written statement will be included for the record in its entirety.

[The statement follows:]

## STATEMENT OF JOHN J. O'SHAUGHNESSY

I am pleased to be with you today to present the Departmental Management portion of the FY 1985 budget request for the Department of Health and Human Services. Four Departmental Management appropriations are considered by this Subcommittee: General Departmental Management, the Office for Civil Rights, the Office of the Inspector General and Policy Research.

Mr. Chairman, at this point I would like to summarize the major activities of each of the four appropriations and highlight the proposed operating changes in each account.

### General Departmental Management

For General Departmental Management activities, we are requesting $133,000,000 and 2,691 positions plus $8,000,000 in obligational authority to be transferred from the Social Security and Medicare Trust Funds. These levels are $13.1 million and 414 positions below the comparable FY 1984 level. This year's request is of particular significance because it presents a plan to undertake several management and staffing level changes in the Office of the Secretary to achieve greater operating efficiencies.

The request I am presenting to you today is the product of lengthy and serious deliberations at the Department that were prompted by the recommendations of the President's Private Sector Survey on Cost Control (Grace Commission). As our budget proposals will bear out, the plan is by no means a simple translation of the Grace Commission's recommendations into a budget request format. Using the Grace report as a point of departure, and employing the policy guidance embodied in the Administration's "Reform '88" initiatives, the Department embarked on a series of reviews of current operating practices which in each case challenged their necessity, efficiency, and appropriateness of organizational location. The common conclusion of these reviews is that the Office of the Secretary's staff and budget resources can be reduced substantially without diminution in the quality of assistance to the Secretary or the provision of essential services to the Department's Operating Divisions (OPDIVs).

In considering proposals for improving how the Office of the Secretary (OS) operates, we have been mindful of the close interrelation of OS Staff Division activities to one another (and their relations to the Operating Divisions) so that we could produce a management plan that was both comprehensive and practical.

For example, decisions about how the Office of the Secretary obtains computer services have ramifications that extend from personnel services and payroll processing services performed by the Assistant Secretary for Personnel Administration to evaluation projects performed by the Assistant Secretary for Planning and Evaluation. Appropriate management, policy and resource decisions were made about how we perform the various activities which rely on computer services. Assessing the full effects of each proposed modification therefore has required consideration in the most comprehensive context. In formulating the budget request before you today, the Department has avoided piecemeal approaches in favor of the greater economies attainable through comprehensive changes. This carefully conceived approach to developing the FY 1985 budget, I believe, results in a sensible and workable course of action.

Beside its comprehensiveness, another defining characteristic of the plan is the extent to which it minimizes adverse effects on employees at risk of separation through reorganization and reduction-in-force procedures. Since more than 70 percent of the General Departmental Management funding supports staff costs, an inevitable consequence of decreasing resources in line with workload reductions is loss of staff. At the direction of Secretary Heckler, every effort will be made to achieve necessary staffing reductions humanely. We are vigorously pursuing all available alternatives to the loss of employment of current employees. These include continuing a freeze on hiring, using a professional counseling and placement contractor to provide career counseling and outplacement services, requesting authority for "early-out" retirements, and transferring staff to the Operating Divisions.

With the perspective afforded by these introductory comments, I would now like to highlight the findings of the OS reviews and how they are incorporated in this budget request. First, the Department has relied too much in recent years on the OS workforce to provide management services and to finalize work products for the Secretary. This trend has supported growth of the OS Staff Divisions which has not been accompanied by reductions in the Operating Divisions.

Secondly, as a consequence of diffuse management authorities, OS operations have largely failed to capture the economies achievable through automation and use of integrated work groups. The plan for automating personnel processing and reconfiguring current data processing services contained in the budget request are a direct response to this finding. The last of the deficiencies found in the reviews is that certain labor-intensive OS functions, for example, facilities engineering reviews, are a relic of past conditions.

As I have already stated, every alternative to reductions-in-force will be exhausted. Beginning last August we imposed a freeze on hiring to take most of the reduction through passive means. To accommodate this reliance on attrition, we are not proposing to eliminate any authorized positions in FY 1984. Attrition does not occur evenly across the OS staff offices and consequently we are unable to pinpoint how many fewer authorized positions are needed in FY 1984.

Our priorities for FY 1985 include the collection of $1.63 billion of outstanding debt owed to the Department by individuals and organizations, compared to FY 1983 and FY 1984 totals of $1.50 billion and $1.52 billion, respectively. We plan to reduce overdue debts from $637 million in FY 1983 to less than $200 million in FY 1985.

The Department will continue to meet the six-month deadline for settling of all unresolved audit reports on grantee or contractor claims in FY 1985. Efforts to reduce the paperwork burden imposed upon the public by HHS programs, and to eliminate overlapping publications will also continue uninterrupted. In general, we do not expect any reduction in the leadership capabilities or essential service capacities of the Office of the Secretary. To the contrary, implementation of the management plan reflected in the FY 1985 budget request will: renew the purposes for which the Office of the Secretary is designed; bring OS operations into the era of modern management; and reduce the cost to the taxpayer of overhead expenses.

Office of the Inspector General

To continue the essential work of the Office of the Inspector General, the FY 1985 budget request includes $58.5 million in budget authority, 1,496 full time permanent positions and $20.0 million in obligational authority transferred from the Social Security and Medicare Trust Funds.

Our FY 1985 request is $10.2 million below the comparable FY 1984 budget authority level, but $3.8 million over the FY 1984 program level. This is the result of a net effect of a $3.8 million increase for cost-of-living adjustments and a $14.0 million rise in trust fund financing of Office of the Inspector General operations.

Two transfers are reflected in the FY 1985 request for the OIG. An additional $5.1 million and 118 positions are included in the OIG request for activities previously funded through the Office of Child Support Enforcement. This transfer continues the Department's efforts to consolidate all audit and program integrity resources under the immediate direction of the Inspector General. We believe that in doing this we will reduce duplication of program integrity resources and better target our investigative and audit programs. In FY 1985, this office will continue to redirect its resources and efforts toward areas where the largest Departmental expenditures of resources are made. Specifically, concentrated efforts will focus on Social Security and Health Care Financing (Medicaid and Medicare) programs. These programs provide services to approximately 150 million people at a high cost and are susceptible to fraud, abuse, and waste.

Office for Civil Rights

To support the Office for Civil Rights (OCR), we are requesting $17.9 million, 459 positions, plus $2.35 million in obligational authority to be transferred from the Social Security and Health Insurance trust funds. The total amount requested represents a decrease of $1,095,000 and 50 positions below the FY 1984 level.

OCR is the chief HHS agency responsible for enforcing civil rights laws in health and human services programs. These laws prohibit discrimination on the basis of race, color, national origin, handicap, and age. There are about 230,000 group and institutional providers subject to the civil rights laws. OCR's responsibility is to ensure that recipients of Departmental funds are aware of their civil rights obligations and have taken steps to comply with them.

This budget request will allow OCR to pursue vigorous civil rights initiatives to prevent discriminatory conditions and to carry out the full range of complaint processing and other compliance activities. The reduction of 50 positions in FY 1985 reflects workload reductions and more efficient management of the compliance program. Over the past four years, the number of new complaints has declined substantially. This trend, coupled with yearly productivity gains, will enable OCR to process complaints with fewer staff. Within the overall compliance program, the bulk of the decrease will be absorbed chiefly in administrative support areas.

## Policy Research

For Policy Research, the FY 1985 request of $8 million will support research in the areas of health, income and employment, and human services policy. This program enables the Secretary to examine issues that cut across agency and subject lines, as well as new approaches developed outside the context of existing programs. The flexibility of this research program allows us to examine issues such as: methods of promoting private sector involvement in the financing and delivery of human services; improvements in the delivery and financing of long-term care; the relationship between public and private sector retirement plans; and reforms in the financing and delivery of public and private health care.

Much of our research is conducted using short-term, focused studies that enable us to respond quickly to changing policy needs and priorities. This enables the Department to be responsive to the needs of both the executive and legislative branches.

In conclusion, Mr. Chairman, the budget request for the appropriations within Departmental Management represents a composite of management initiatives to streamline operations, to modernize through automation and to reduce overhead costs. We believe this level of resources will allow Departmental Management to maintain its leadership role and to provide the essential services required in the Department.

I urge your approval of this request and thank you for your consideration.

## BIOGRAPHY OF JOHN J. O'SHAUGHNESSY

John J. O'Shaughnessy was named acting assistant secretary for management and budget, Department of Health and Human Services, July 6, 1983, by HHS Secretary Margaret M. Heckler and became the assistant secretary, Oct. 2, 1983. His formal swearing-in ceremony was Oct. 28, 1983.

O'Shaughnessy is the Secretary's principal advisor for management, administrative and budget policies in a department whose budget is the third largest in the world (after those of the U.S. government and the Soviet Union). His responsibilities include overseeing development of the department's budget and providing department-wide guidance on general management operations and major policies in such areas as grants, contracts, financial management and automatic data processing systems.

O'Shaughnessy was born in New York City on July 20, 1944. He received a bachelor's degree (with philosophy as his major field) from St. Alphonsus College in 1967, a master's degree from Ohio University in 1970, a master's degree in public administration from Harvard University in 1977, and a master of philosophy degree from George Washington University in 1982. He also studied international relations at Catholic University in Louvain, Belgium.

From September 1969 to August 1970 O'Shaughnessy was a teaching assistant at the State University of New York at Buffalo. From September 1970 to December 1971 he was in the executive trainee program in the Office of the Secretary of Defense. Between December 1971 and November 1978 he served in the Office of the Secretary of Defense as a member of the task force handling Mutual and Balanced Force Reductions in Europe as well as the Conference on Security and Cooperation in Europe, among other responsibilities. From January 1978 to 1983 he served as the defense advisor to Republican members of the House Budget Committee. In October 1981 he became the Republican staff director of the House Budget Committee.

O'Shaughnessy is married and resides in Alexandria, Va.

## INTRODUCTION OF ASSOCIATES

Mr. O'SHAUGHNESSY. Good morning. We have with us Dr. Robert Rubin, Assistant Secretary for Planning and Evaluation, Mr. Richard Kusserow, the Inspector General, and Mr. John Hopkins, the Director of OS Budget Services. I also have with me Mr. Tony Itteilag, who is the Deputy Assistant Secretary for Budget in the Department.

May I proceed with my statement?

Senator WEICKER. Yes.

## OPENING STATEMENT

Mr. O'SHAUGHNESSY. Mr. Chairman, I am pleased to be with you this morning to present the fiscal 1985 budget request for the departmental management accounts of the Department of Health and Human Services. As the chairman has mentioned, four departmental management appropriations are considered by the subcommittee: general departmental management; the Office for Civil Rights; the Office of the Inspector General; and policy research.

Mr. Chairman, at this point, I would like to summarize the major activities of each of the four appropriations and highlight the proposed operating changes in each account.

For general departmental management activities, we are requesting $133 million and 2,691 positions plus $8 million in obligational authority to be transferred from the Social Security and medicare trust funds. These levels are $13.1 million and 414 positions below the comparable fiscal year 1984 level.

This year's request is of particular significance because it presents a plan to undertake several management and staffing level changes in the Office of the Secretary to achieve greater operating efficiencies.

The request that I am presenting to you today is the product of lengthy and serious deliberations at the Department that were prompted by the recommendations of the President's private sector survey on cost control, the so-called Grace Commission. As our budget proposals will bear out, the plan is by no means a simple translation of the Grace Commission's recommendations into a budget request format.

Using the Grace Commission's report as a point of departure, and employing the policy guidance embodied in the administration's reform 1988 initiatives, the Department embarked on a series of reviews of current operating practices which in each case challenged their necessity, efficiency, and appropriateness of organizational location. The common conclusion of these reviews is that the Office of the Secretary's staff and budget resources can be reduced substantially without diminution in the quality of assistance to the Secretary or the provision of essential services to the Department's operating divisions.

In considering proposals for improving how the Office of the Secretary operates, we have been mindful of the close interrelation of the Office of the Secretary staff division activities to one another and their relations to the operating divisions, so that we can produce a management plan that is both comprehensive and practical.

For example, the decisions about how the Office of the Secretary obtains computer services have ramifications that extend from personnel services and payroll processing services performed by the Assistant Secretary for Personnel Administration to evaluation projects performed by the Assistant Secretary for Planning and Evaluation.

Appropriate management, policy, and resource decisions were made about how we perform the various activities which rely on computer services. Assessing the full effects of each proposed modification, therefore, has required consideration in the most comprehensive context. In formulating the budget request before you today, the Department has avoided piecemeal approaches in favor of the greater economies attainable through comprehensive changes. This carefully conceived approach to developing the fiscal year 1985 budget, I believe, results in a sensible and workable course of action.

Besides its comprehensiveness, another defining characteristic of the plan is the extent to which it minimizes adverse effects on employees at risk of separation through reorganization and reduction-in-force procedures. Since more than 70 percent of the general departmental management funding supports staff costs, an inevitable consequence of decreasing resources in line with workload reductions is loss of staff. At the direction of Secretary Heckler, every effort will be made to achieve necessary staffing reductions humanely. We are vigorously pursuing all available alternatives to the loss of employment for current employees. These include continuing a freeze on hiring, using a professional counseling and placement contractor to provide career counseling and outplacement services, requesting authority for early-out retirements, and transferring staff to the operating divisions.

With the perspective afforded by these introductory comments, I would now like to highlight the findings of the Office of the Secretary reviews and how they are incorporated in this budget request. First, the Department has relied too much in recent years on the Office of the Secretary work force to provide management services and to finalize work products for the Secretary. This trend has supported growth of the Office of Secretary staff divisions, which has not been accompanied by reductions in the operating divisions.

Second, as a consequence of diffuse management authorities, the Office of Secretary operations have largely failed to capture the economies achievable through automation and the use of integrated work groups. The plan for automating personnel processing and reconfiguring current data processing services contained in the budget request are a direct response to this finding. The last of the deficiencies found in the reviews is that certain labor-intensive Office of Secretary functions, for example, facilities engineering reviews, are a relic of past conditions.

As I have already stated, every alternative to reductions in force will be exhausted. Beginning last August, we imposed a freeze on hiring to take most of the reduction through passive means. To accommodate this reliance on attrition, we are not proposing to eliminate any positions in fiscal year 1984. Attrition does not occur evenly across the

Office of Secretary staff offices and, consequently, we are unable to pinpoint how many fewer authorized positions are needed in fiscal year 1984.

Our priorities for fiscal year 1985 include the collection of $1.63 billion of outstanding debt owed to the Department by individuals and organizations, compared to fiscal year 1983 and 1984 totals of $1.5 billion and $1.52 billion, respectively. We plan to reduce overdue debts from $637 million in fiscal year 1983 to less than $200 million in fiscal year 1985.

The Department will continue to meet the 6-month deadline for settling of all unresolved audit reports on grantee or contractor claims in fiscal year 1985. Efforts to reduce the paperwork burden imposed upon the public by HHS programs and to eliminate overlapping publications will also continue uninterrupted. In general, we do not expect any reduction in the leadership capabilities or essential service capacities of the Office of the Secretary. To the contrary, implementation of the management plan reflected in the fiscal year 1985 budget request will renew the purposes for which the Office of the Secretary is designed, will bring OS operations into the era of modern management and will reduce the cost to the taxpayer of overhead expenses.

With regard to the Office of Inspector General, in order to continue the essential work of that office, the fiscal year 1985 budget request includes $58.5 million in budget authority, 1,496 full-time permanent positions and $20 million in obligational authority transferred from the Social Security and medicare trust funds.

Our 1985 request is $10.2 million below the comparable fiscal year 1984 budget authority level, but $3.8 million over the fiscal year 1984 program level. This is the result of a net effect of a $3.8 million increase for cost-of-living adjustments and a $14 million rise in trust fund financing of the Office of the Inspector General operations.

Two transfers are reflected in the fiscal year 1985 request for the Office of Inspector General. The first includes an additional $5.1 million and 118 positions for activities previously funded through the Office of Child Support Enforcement. This transfer would continue the Department's efforts to consolidate all audit and program integrity resources under the immediate direction of the Inspector General. We believe that in doing this, we will reduce duplication of program integrity and better target our investigative and audit programs. The other transfer involves the inclusion of funding for State medicaid fraud control units in the medicaid account.

In 1985, this office will continue to redirect its resources and efforts toward areas where the largest departmental expenditures of resources are made. Specifically, concentrated efforts will focus on the Social Security and Health Care Financing Administration programs. These programs provide services to approximately 150 million people and are susceptible to fraud, abuse, and waste.

To support the Office for Civil Rights, we are requesting $17.9 million, 459 positions, plus $2.35 million in obligational authority to be transferred from the Social Security and health insurance trust funds. The total amount requested represents a decrease of $1.095 million and 50 positions below the 1984 level.

The Office for Civil Rights is the chief HHS agency responsible for enforcing civil rights in health and human services programs. These laws prohibit discrimination on the basis of race, color, national origin, handicap, and age. There are about 230,000 group and institutional providers subject to the civil rights laws. This office's responsibility is to ensure that recipients of departmental funds are aware of their civil rights obligations and have taken steps to comply with them.

This budget request will allow the Office for Civil Rights to pursue vigorous civil rights initiatives to prevent discriminatory conditions and to carry out the full range of complaint processing and other compliance activities. The reduction of 50 positions in fiscal year 1985 reflects workload reductions and more efficient management of the compliance program.

Over the past 4 years, the number of new complaints has declined substantially. This trend, coupled with yearly productivity gains, will enable OCR to process complaints with fewer staff. Within the overall compliance program, the bulk of the decrease will be absorbed chiefly in administrative support areas.

For policy research, the fiscal year 1985 request of $8 million will support research in the areas of health, income, and employment and human services policy. This program enables the Secretary to examine issues that cut across agency and subject lines, as well as new approaches developed outside the context of existing programs. The flexibility of this research program allows us to examine issues such as: methods of promoting private sector involvement in the financing and delivery of human services, improvements in the delivery and financing of long-term care; the relationship between public and private sector retirement plans; and reforms in the financing and delivery of public and private health care.

Much of our research is conducted using short-term, focused studies that enable us to respond quickly to changing policy needs and priorities. This enables the Department to be responsive to the needs of both the executive and legislative branches.

In conclusion, Mr. Chairman, the budget request for the appropriations within departmental management represents a composite of management initiatives to streamline operations, to modernize thorough automation, and to reduce overhead costs. We believe this level of resources will allow departmental management to maintain its leadership role and to provide the essential services required in the Department.

I urge your approval of this request, and I thank you for your consideration.

PREPARATION OF BUDGET

Senator WEICKER. Last week we had testimony from the Secretary that she consulted with the agencies within the Department regarding their budget needs after she went to the White House and received a target from the so-called Budget Review Board.

As Assistant Secretary for Management and Budget, what role did you play in advising the Secretary in the preparation of the budget?

Mr. O'SHAUGHNESSY. With regard to that target, Mr. Chairman, I was not on board, nor was I on board by the time the Secretary met with the heads of the operating divisions to give them general guidance as to how to proceed with the budget development. I came to the Department in July, at which point the operating divisions and Office of the Secretary were in the process of developing their responses to the Secretary. At that point, my role mainly was one of putting together the budget request, not only in line with the overall guidance that had been given to the operating divisions, but also helping them as they set priorities for increases above the mark that they had been given.

My role was to work with the Secretary as she considered the baseline responses of the operating divisions, as well as their priorities for additional funding. This continued through the process of negotiating with OMB.

Senator WEICKER. It has long been the policy and practice of the Appropriations Committee that budget justifications are due the day that budgets are submitted to Congress, February 1. Why then did it take nearly 2 months to present the budget justifications for departmental management?

Mr. O'SHAUGHNESSY. That was entirely my responsibility, Mr. Chairman. It was an inexcusable delay. We needed to conduct ourselves properly by way of union agreements and other kinds of processes in terms of performance. I needed to set aside a block of time for the Secretary to review all of the recommendations made to her, enable her to make final decisions, and then consult with the unions, as is part of our union agreement, before bringing the plan to the Congress.

It was a scheduling delay for which we could make this presentation to the Secretary that resulted in the late budget justification.

Senator WEICKER. Did you ever notify the commmittee that there would be an extended delay?

Mr. O'SHAUGHNESSY. No; we didn't. We knew we weren't ready, but we never said we wouldn't be ready until a certain point in time.

Senator WEICKER. Do you expect that you'll have your justification before the committee by February 1 next year?

Mr. O'SHAUGHNESSY. I definitely think we will move quickly next year. I can't say February 1, but I do not believe you'll see a repetition of this.

Senator WEICKER. Well, what do you mean by that?

Mr. O'SHAUGHNESSY. I'm not sure what the normal date is, but we will be on time, I can state that.

Senator WEICKER. Claudia indicates to me that normally the budget comes up in late January and the justifications are due by then.

Mr. O'SHAUGHNESSY. Whatever time they are due, we'll have them in.

### STAFFING REDUCTIONS

Senator WEICKER. On page 5 of your budget justification, you show a planned reduction of 414 positions. A departmental memo indicates that the Office of the Secretary will reduce positions by 1,264, 50 percent by attrition. That's 632. My arithmetic indicates 207 unaccounted for.

Mr. O'SHAUGHNESSY. One of the reasons for that discrepancy, Mr. Chairman, is the fact that, the 1,264 reduction is over a 2-year period. The reduction of 414 positions measures a reduction to the fiscal year 1984 comparable level which has been adjusted for transfers.

The other reason for the change is that the 414 represents the authorized full-time positions, while the 1,264 is in terms of full-time equivalents that include temporary and part-time employment positions as well. My staff can provide a line-by-line accounting of the differences for the record.

[The information follows:]

### POSITION REDUCTION OF 414 VERSUS FTE SAVINGS OF 1,264

The reduction of 414 authorized positions requested in the fiscal year 1985 general departmental management budget does not correspond directly to the 1,264 full-time equivalent [FTE] employment reduction described in the March 19 announcement to streamline the Office of the Secretary because the measures differ in the following ways:

Authorized positions is a measure of the number of full-time permanent appointments allowed at a point in time. FTE, on the other hand, is an annual, cumulative measure of staff resources which aggregates other than full-time permanent employment with full-time permanent appointments.

The authorized position reduction of 414 is a 1-year, comparable decrease from fiscal year 1984 to fiscal year 1985. The 1,264 FTE reduction is a 2-year change from fiscal year 1983 to fiscal year 1985 including transfers.

The 414 position reduction reflects decreases only in the general departmental management [GDM] appropriation account, while the 1,264 FTE reduction in the Office of the Secretary combines GDM decreases with reductions in the Office for Civil Rights [OCR], policy research [PR], and working capital fund [WCF] accounts.

The table below delineates the relationship between the position reduction and the FTE savings:

| | Authorized positions | Annualized FTE |
|---|---|---|
| Fiscal year 1983 level | 4,174 | 4,342 |
| GDM | (3,507) | (3,723) |
| OCR/PR/WCF | (667) | (619) |
| Less: Fiscal year 1984 reductions: | | |
| Approved in fiscal year 1984: | | |
| Budget | -57 | -119 |
| GDM | (-39) | (-109) |
| OCR/PR/WCF | (-18) | (-10) |
| Transfers in fiscal year 1984 | -363 | -530 |
| GDM | (-363) | (-530) |
| Other fiscal year 1984 reductions: | | |
| Shown in fiscal year 1985: | | |
| Budget | | -34 |
| PR/WCF | | (-34) |
| Subtotal, fiscal year 1984 level | 5,754 | 3,659 |
| Less: Fiscal year 1985 proposed: | | |
| Reductions | -572 | -581 |
| GDM | [1] (-414) | (-475) |
| OCR/PR/WCF | (-158) | (-106) |
| Total 1983–1985 reduction | -992 | [2] -1,264 |
| GDM | (-816) | (-1,114) |
| OCR/PR/WCF | (-176) | (-150) |

[1] Represents fiscal year 1984–85 reduction in authorized positions for general departmental management appropriation only.

[2] Represents fiscal year 1983–85 reduction in full-time equivalents for four appropriation accounts.

## COMMUNICATION WITH SUBCOMMITTEE

Senator WEICKER. OK.

The same departmental memo indicates that you've already reduced the personnel in the Office of the Secretary by hundreds of people, yet the subcommittee has not received any communication from the Department informing us about these reductions, nor have we received a request for permission to implement these reductions.

What have you done with the money appropriated for these positions?

Mr. O'SHAUGHNESSY. In fiscal year 1984, the transferred positions will be paid for from funds appropriated to departmental management. Most of the moneys that would otherwise pay for the salaries of separated employees will instead fund the termination costs at the end of the year. That would take up most of the savings for fiscal year 1984. There is money that will also be used within the departmental management appropriation for transfering data processing functions and augmenting the payment management system.

Senator WEICKER. Why did you not submit a reprogramming notice?

Mr. O'SHAUGHNESSY. We didn't believe we needed to submit a reprogramming notice. It's our understanding that the ground rules under which we operate require reprogramming notification if we transfer money between the departmental direction and the departmental operations activities. And we don't believe that's been done. We do intend to supply any reprogramming information to the committees, if necessary.

Senator WEICKER. Will you please describe what you mean when you say you'll be limiting the amount of technical assistance to the staff of the Appropriations Committee?

Mr. O'SHAUGHNESSY. The only limit that has occurred is that we've reduced one driver that we had for messenger service, and that person voluntarily moved to another job. We've looked at all the other work that we've done for the committees, and we don't think there will be anything else reduced.

Senator WEICKER. Senator Proxmire.

### EMPLOYEE LOAN DEFAULTS

Senator PROXMIRE. Thank you, Mr. Chairman.

Mr. Chairman, I notice you pressed Mr. O'Shaughnessy on how he will respond to the Appropriations Committee's needs in 1985. Well, we may have a new President and a new administration, and Mr. O'Shaughnessy, I don't know if you'll hold this job or not at that time. You've got a distinguished background.

Mr. O'SHAUGHNESSY. I would expect that I might.

Senator PROXMIRE. It might be President Mondale, President Hart, President Jackson or President Bumpers. As a matter of fact, if Chairman Weicker would just change his party, we'd nominate him.

Senator WEICKER. That's something that's very far away.

Senator PROXMIRE. I can just see the chairman at the convention.

Senator WEICKER. I'll say this. I'd rather be in a convention in San Francisco rather than Texas.

Senator PROXMIRE. I hope Mr. Rubin will be with us. I assume in his absence, you will have somebody here who can answer my questions.

Mr. O'SHAUGHNESSY. Excuse me, Dr. Rubin has just walked in.

Senator PROXMIRE. Dr. Rubin, I'm delighted to see you.

Mr. O'SHAUGHNESSY, last week I asked the Secretary why only five HHS employees were being assessed for Department of Education indebtedness when 625 employees had defaulted on $800,000 in student loans. The response was that the Department had grossly underestimated the number of employees working for HHS who were in default and that you did not as yet have the authority to assess these employees.

I went back to last year's record and found that Public Law 97-365 allows you to collect debts due to the Government through a salary offset mechanism and that you claimed to be assessing five HHS employees for Department of Education indebtedness.

Was last year's statement incorrect?

Mr. O'SHAUGHNESSY. Let me review that, Senator.

Last week I was the one who indicated that only five employees were in default. The number 625 was the figure that was found to be correct. It is my understanding that the discrepancy lies in the criteria used for determining the default. There were five employees who were indebted to the Government and had to repay through a court-ordered process. The number 625 results from a Department of Education review of employees who owed the Government money, and only 450 of those employees are still with the Department. We have sent letters to them, based on the September 1983 identification by the Department of Education, asking them to pay as quickly as possible. We do intend to take action, in order to force compliance, if we have to. Before we can take that action, we need to go through a review and comment period. And we intend to do that.

Senator PROXMIRE. But you do have the power, according to law——

Mr. O'SHAUGHNESSY. Yes; we do.

Senator PROXMIRE [continuing]. To collect through a salary offset mechanism.

I'm sure you understand that we have an appalling situation when thousands of people who have gotten student loans and have done very well are not repaying the loan funds. I think we ought to set an example.

Mr. O'SHAUGHNESSY. We intend to do that. I see no excuse for not pursuing this vigorously, but we do have to follow the proper procedures.

Senator PROXMIRE. I have some questions for Dr. Rubin, if he is here.

Senator WEICKER. Yes; we can go into that.

Senator PROXMIRE. Is that all right with you?

Senator WEICKER. Absolutely. Go right ahead.

### INSTITUTE FOR RESEARCH ON POVERTY

Senator PROXMIRE. Dr. Rubin, on March 8, you submitted a report to the Congress on your office's plans for funding the Institute for Research on Poverty at the University of Wisconsin. Would it be fair to characterize that report as saying that you no longer intend to support the work of the Institute through a core grant?

Dr. RUBIN. Core grant? Yes.

Senator PROXMIRE. In 1979, Dr. Rubin, as I'm sure you know, a committee of the National Academy of Sciences evaluated Federal support for policy research and had this to say about the work of the Poverty Institute, and I quote:

> The committee concludes that the Institute has been an exceptionally successful vehicle for support of research by the Federal Government. Important Government objectives have at least in substantial part been realized by its support: maintenance of a high-quality, sustained, cumulative program of research on poverty, production of knowledge that has influenced policy, and the allocation of research effort to important topics that the OEO or HEW might not otherwise have studied.

What has happened in the past 5 years to change the committee's conclusion that the Institute, with Federal support, has worked on important topics that you might not have studied otherwise?

Dr. RUBIN. I think that the issue here, Senator, is not the quality of work done at the Institute on Poverty, but that they have been successful in their mission, which has been to train people to do research on poverty. These people are now dispersed about the United States.

To give the University of Wisconsin's Institute on Poverty a core grant when, in essence, the function they serve is to push that money out around the United States, particularly through researchers they have trained, seems to me, to ask them to assume an overhead function that the Federal Government could do in a competitive way through peer review. This is a way that could be more productive than what the University of Wisconsin has done—where they do not have peer review and they do not have open competition.

### CORE GRANTS

Senator PROXMIRE. The Academy Committee characterizes the core grant as permitting, and I quote, "the grouping in one place of a substantial number of people working on related projects." The committee goes on to say, "Under individual project funding, the pattern of project selection would not necessarily produce this conglomeration and its benefits." The committee concluded that in the absence of core support, "the amount of high-quality poverty research would drop sharply."

Why do you reject the committee's conclusion that individual project grants might not produce these benefits?

Dr. RUBIN. My understanding, Senator, of that report is that they talked about a critical mass in order to have an appropriate interchange, and there is nothing in the plans that we have currently to fund poverty research that would prevent that critical mass, if the committee is correct, from giving these people a leg up. So they would be probably very successful, as they have been in the limited competitions that we have had since I have been in office.

Senator PROXMIRE. But the Academy Committee says that under individual project funding this grouping effect might well end and that, in their view, grouping provides unique benefits.

Dr. RUBIN. I don't see why priority warrants that they end at all. My suspicion is that they will probably continue.

And, indeed, the University of Wisconsin is probably pretty successful in getting outside funding, and because they have this core group, a critical mass if you will, they should be very successful in competing for the amount of money that we have available in poverty research.

Senator PROXMIRE. Has the National Academy of Sciences endorsed your decision to abandon the core grant approach?

Dr. RUBIN. We didn't consult the National Academy of Sciences.

Senator PROXMIRE. The answer is "no" then?

Dr. RUBIN. The answer is that they haven't been asked.

Senator PROXMIRE. Then the answer is that the academy hasn't endorsed your decision. You say they haven't been asked, so they obviously haven't endorsed the decision.

Dr. RUBIN. Well, they haven't rejected it either.

Senator PROXMIRE. Obviously, you feel strongly about your approach and others feel differently.

Why wouldn't it make sense to get some disinterested advice from the academy?

Dr. RUBIN. I think it might be wise to get advice from disinterested observers. Taking into account the kind of budgetary restraints that we have and our commitment to create open and competitive grants, the use of observers is certainly something we ought to consider.

Senator PROXMIRE. Would you consider the academy as a disinterested objective source of information?

Dr. RUBIN. In some areas, the academy has been disinterested, and not in others. I think you have been critical of the academy from time to time because of some of their recommendations in the medical and scientific community.

Senator PROXMIRE. Well, everybody is human. Everybody has at least one golden fleece in their life, I suppose.

Dr. RUBIN. I think the Wall Street Journal golden fleece award went to you.

Senator PROXMIRE. Probably more than one.

## LONG-RANGE POVERTY RESEARCH

Dr. Rubin, it is interesting to note that the National Academy of Sciences Committee on Evaluation of Poverty Research explicitly addressed the question of whether your staff had the capability to successfully set a coherent long-range poverty research agenda. The committee noted that the program you administer has a very long-time horizon and an explicitly Government-wide charge. The committee went on to say—and here I am quoting:

> The research is intended to pursue questions relating to poverty whether they now bear directly on HEW's program responsibilities or not. This situation sets up an inevitable competition for time, funds, and personnel within ASPE between analysis of immediate importance to the Department and longer-term research on poverty. An already small staff for poverty research tends to be kept small by such pressure.

Wouldn't this statement be all the truer this year when you are planning to cut policy research staff back by more than 20 percent from 18 to 14 positions?

Dr. RUBIN. I think we need to be more vigorous in the kinds of things that we do. It should also be pointed out that the policy research budget in 1979, which is the time I believe this report was written, was something on the order of $30 million. We are now requesting $8 million. So, the fact that we are decreasing staff is commensurate with the decrease.

Senator PROXMIRE. Your poverty research budget was $30 million and your 1985 request is $8 million?

Dr. RUBIN. That is correct.

Senator PROXMIRE. Well, now, you consider the problem of poverty in this program. There are more people in poverty now than they were 2 years ago, is that not right?

Dr. RUBIN. Yes, sir.

Senator PROXMIRE. Does it make sense to spend only $8 million researching the colossal, serious, heartbreaking poverty problem we have in this country?

Dr. RUBIN. Well, $8 million is the request for the entire program.

### POVERTY RATES

Senator PROXMIRE. It has been brought to my attention that the official poverty rate has increased from 11.4 percent in 1978 to 15 percent in 1982. Although we have moved somewhat out of the recession, that hasn't helped people in poverty.

Dr. RUBIN. Actually, the rise in poverty has decreased. The rate of increase has decreased every year in this administration.

Senator PROXMIRE. In other words, poverty is increasing, but it is increasing at a decreasing rate.

Senator WEICKER. What does that mean?

Dr. RUBIN. I think Senator Proxmire restated it well.

Senator WEICKER. I am not interested in what Senator Proxmire said. I am asking you what that means.

Dr. RUBIN. It means that the programs which are in place, to some extent have stemmed the rate of increase in poverty. The rate of increase in poverty numbers even in 1982, which is the last year that the Census Bureau has reported on, which was a year of terrible recession, was substantially less than it was in 1979. The rate has gone from approximately 11.1 percent to 7.1 percent over the space of 3 years, so that the slope of the curve, if you will, is going down. Many people have the misimpression that the slope is still going up.

Senator WEICKER. Well, let's just talk some bottom line here. You are saying, in other words, that there are less persons in poverty than there were before this administration?

Dr. RUBIN. No; what I am saying——

Senator WEICKER. That is the bottom line. I am not interested in juggling a lot of figures. There are more people in poverty?

Dr. RUBIN. That is correct.

Senator WEICKER. As the Senator has already stated?

Dr. RUBIN. That is correct.

Senator WEICKER. Why is that a statement of success?

Dr. RUBIN. What I am saying, Senator, is even at a time when this country was in very severe recession, 1981–82, the growth in the poverty numbers, the absolute number of people in poverty, was less than the increase from 1978 to 1979, 1979 to 1980, 1980 to 1981.

The rate of increase has been progressively less, even at a time when the economic conditions have been substantially worse, 1982 versus 1979 and 1980. One interpretation of that might well be that some of the programs that this administration and, indeed, the Congress has supported have been successful in keeping people out of poverty.

In essence, what we are saying is that things could have been a lot worse, given the economic conditions, than they are under this administration.

Senator PROXMIRE. You make a fascinating argument. It is like saying if you go on a diet after your weight has gone from 200 pounds to 225 pounds in 1 month and the diet enables you only to slow down that rate of gain, so that you gain 15 pounds in the second month and 10 pounds in the third month, the diet is working great.

It seems to me the only way a program can really show it is paying off is to reduce the number of people in poverty, not to reduce the rate of increase of the people in poverty.

Dr. RUBIN. Senator, I agree with you completely, but when the economy was going to hell in a handbasket in 1982, when we had a serious recession and unemployment was moving along at a rapid pace, one would have reasonably expected the numbers of people in poverty to go up 15 percent above where they were in 1982, and they didn't.

And if one extrapolates that and looks at the rate and that rate of gain is decreasing, one eventually hopes that the trend will turn around to eventually get absolute decreases in poverty. That is clearly the hope of everybody.

Senator WEICKER. Well, the only thing—and I don't mean to intrude on your time, Bill—I don't understand—I realize with statistics what they can do with them, but the number of individuals below poverty has increased from 24.5 million in 1978 to 34.4 million in 1982.

Now, is that figure correct?

Dr. RUBIN. It sounds roughly correct, yes, sir.

Senator WEICKER. Well, I don't understand then what it is that you are trumpeting around here. I really don't. I don't understand it at all.

Senator PROXMIRE. At any rate, you indicated that there was a sharp drop in the amount of money spent to engage in research on poverty at a time when the actual number of people who are below the poverty line is on the increase?

Dr. RUBIN. Yes, sir.

Senator WEICKER. In other words, what he is saying—what counsel tells me that Dr. Rubin is saying is that even though it went from—we will see if counsel is correct— from 24.5, 30.4, and 34.4, you are saying it could have been 70 and we are supposed to be grateful for the fact that it isn't?

Dr. RUBIN. I certainly am grateful that the number of people in poverty is not as great as it could be, and we hope to see the trend continue downward.

Senator WEICKER. Well, that is a hell of a standard for performance, I will tell you that.

I suggest that nobody is blaming the administration for this, but to go ahead and exalt it I think is a little bit far-reaching.

I am sorry, Bill.

## CROSS-CUTTING RESEARCH

Mr. O'SHAUGHNESSY. Senator, if I might add a comment with regard to the size of the funding level in this account?

I would like to point out that the account is really for cross-cutting research within the Department. It is not the sole research vehicle within the Department, and obviously what we are trying to do in this area, as in other areas, is move toward more reliance on our operating divisions for initiation of this kind of work for the Secretary's consideration.

Let me also point out with regard to poverty levels, if I might—the focus is not necesarily on poverty levels, but on the delivery of services to individuals in need of them in the United States.

If you look at the error rates we have in some of our programs, 2.6 percent is the latest on medicaid funding, 7.1 percent on AFDC. Right now in the AFDC account, the latest figures that I have indicate that about $960 million is being expended erroneously by State and Federal Government officials in that program. We are trying to get that down. It is about $960 million, the latest figure that I have for Federal funding.

It seems to me that any improvements we can make straightening out and reducing the error rates in those programs could mean a sizeable increase in dollars available for serving needy individuals, and that is something else that we place a high priority on.

Senator PROXMIRE. How many staff-years do you plan to devote to long-range poverty research next year?

Mr. O'SHAUGHNESSY. I would have to supply that for the record.

Senator PROXMIRE. Would you please give us a projection for next year for the record?

[The information follows:]

Of the $8 million requested for the policy research account, we expect to allocate about $2.5 million for research on poverty-related issues. These funds will be managed by approximately four FTE's. Other staff will be engaged in related policy analysis, legislative development, and program oversight, and will work with the products of this research. In addition other research in HHS will continue to address the problems of the poor—for example, maternal and child health, Head Start, disease prevention, and health promotion, et cetera.

### PEER REVIEW

Senator PROXMIRE. Do you use academic peer review panels either to frame a long-range agenda on poverty research or to review grant applications, or do you rely solely on the judgment of your staff and that of other agencies?

Dr. RUBIN. We use both outside academics and departmental staff for peer review projects.

Senator PROXMIRE. Do you bring them in to formulate a long-range agenda or just for reviews?

Dr. RUBIN. Currently, in looking at long-range agendas, we use the National Advisory Committee of the Institute on Poverty, which, as you know, is composed entirely of outside people. Some of them might object to being called academic.

Senator PROXMIRE. Will you continue to use that advisory committee?

Dr. RUBIN. For the remainder of fiscal year 1985, absolutely.

Senator PROXMIRE. What would you do after that?

Dr. RUBIN. After that, since we would no longer fund in a core manner the Institute on Poverty, we would need to come up with a different mechanism.

Senator PROXMIRE. At a time when your own payroll is being cut, why wouldn't it be even more important to support poverty research through a core grant, whether the grant is provided to the Institute for Research on Poverty or to another organization?

Dr. RUBIN. I think, as I said earlier, that the bulk of the money that the Institute receives is really funneled out to other investigators throughout the country, and I think we can do that in a better way through the competitive process.

Senator PROXMIRE. Well, let me just ask a question along those lines. Your report to this committee on the Poverty Institute concluded with these words:

> In sum—this is a quotation—it is our plan to continue research on poverty, but to do so in a competitive environment. This approach will guarantee the most cost-effective use of limited resources.

Now, leaving aside the fact that the Institute on Poverty does not allocate funds without research committee review, the Institute will produce 26 final reports from four research contracts, nine reports from the Small Grants Program, and 12 papers from the Williamsburg Conference from its fiscal year 1983 award. The average cost per paper or report is about $30,000.

How does this compare with the cost of the other poverty research being funded by your office?

Dr. RUBIN. I couldn't tell you the comparison for similar projects because there really is no adequate comparison. It would be an apples-and-oranges comparison.

Senator PROXMIRE. Why wouldn't it be a reasonable comparison?

Dr. RUBIN. Because the size of the award is the amount of time and the scope of the report, the kinds of things that we have asked other people to do, may be broader in scope, and consequently——

Senator PROXMIRE. Well, do what you can. I realize it is difficult, but give us a comparison to the extent that you can and provide any report that you can.

Dr. RUBIN. I would be delighted to.

[The information follows:]

### COMPARISON OF POVERTY RESEARCH PROJECTS

NOTE.—Comparisons are difficult because report length, coverage, and quality differ substantially across grants. For illustration, however, three fiscal year 1982 poverty-related grants are described below.

| Institution | Award | Number of reports | Cost per report |
|---|---|---|---|
| Rand Corp | $89,084 | 2 | $44,542 |
| University of Michigan | 188,246 | 2 | 94,123 |
| Harvard | 237,686 | 11 | 21,608 |

### BUDGET CUT EFFECTS

Senator PROXMIRE. I have some other questions for Dr. Altman and Mr. Kusserow, but I am through with the questions for Dr. Rubin.

Senator WEICKER. Has your office conducted a study of the effects of the 1981 Reconciliation Act and other budget cuts on people in poverty?

Dr. RUBIN. We have worked with other parts of the Department to take a look at that.

Senator WEICKER. And?

Dr. RUBIN. Of those people that were affected by the over-cuts in AFDC, a substantial majority of them continued to work. Very few of them went back on AFDC, and those that went on did so for brief periods of time.

Senator WEICKER. Don't you think that there ought to be some precision to what it is that you come up with in this area?

You are relying pretty—you are dealing in lives. Do you have something you can submit for the record as to your investigation and your conclusions on this matter?

Dr. RUBIN. Yes.

Senator WEICKER. Or would you like me to say "participation?" I don't understand what that means.

Do you have a report that you can submit to us, a survey that could be submitted to us, either yours or somebody else's?

Dr. RUBIN. Yes.

Senator WEICKER. What are we talking about?

Dr. RUBIN. Well, there is a report done by the Research Triangle Institute that looked at the impact of the 1981 Omnibus Reconciliation Act cuts in AFDC, and we can certainly submit that to you.

Senator WEICKER. Well, that is only one area.

Dr. RUBIN. We also have funded work at Harvard University, taking a look at the dynamics of people on welfare that we could also submit to you, basically showing that there are a lot of people, even with young children, who work their way off welfare. It looks like a third of the people who have worked their way off welfare have children under six, and that has implications of how one goes about structuring child care services to encourage those people to continue that, as well as with some of the offsets.

We would be happy to submit the reports to the committee.

[The information follows:]

Final reports on the following projects have been provided to the committee:

*Evaluation of the 1981 AFDC Amendments (Research Triangle Institute).*—Study findings regarding the impact on AFDC participation and work effort include:

Earners in the 1981 sample were more likely than pre-OBRA earners to be off the AFDC rolls a year later.

OBRA had little effect on cases that did not have earnings at the time of OBRA implementation.

The major impact of OBRA on the eligibility of earner cases was felt within a relatively short period of time.

Few of the cases that did not have earnings in the base period had earnings in later months following OBRA implementation.

A consistent reduction was found in average grant amount for earners and nonearners during both 1981 and 1982. It cannot be concluded however that this difference is statistically significant.

The analysis concludes that there has been a reallocation of resources among earners, with cases involving high earnings more likely to have been discontinued. In contrast, the remaining earner cases were primarily those with lower earnings in the base period and correspondingly higher grants.

*The Dynamics of Dependence: The Routes to Self-Sufficiency (Urban Systems Research and Engineering, Inc.)*.—The AFDC program was found to serve different purposes for two different groups. Most of the women who go on AFDC have short spells; yet, at the same time, the bulk of AFDC expenditures are accounted for by women who have spells of 8 years or more. The report concludes that State AFDC characteristics can influence the dynamics of AFDC receipt both through their influence on behavior and through a purely mechanical relationship between level of benefits and the likelihood that any given income change will push a recipient across the break-even threshold. The data point to the need to understand the dynamics of dependence and to explore avenues recipients can and do use to become self-sufficient.

[CLERK'S NOTE.—The Complete reports are in the subcommittee files.]

### FISCAL YEAR 1985 BUDGET REQUEST

Senator WEICKER. Your fiscal year 1985 budget request is 20 percent less than the $10 million appropriated in fiscal year 1984, and 70 percent below that appropriated in fiscal year 1980, and yet in your statement you state that your division is the only flexible research authority available to the Secretary. How do you jibe the budget request with the letter?

Dr. RUBIN. In terms of making some decision relative to the amounts of dollars that would be available to this Department, throughout its budget request, we have chosen to emphasize the services. We think the $8 million would be adequate to do the kind of research that we need, the kind of flexible policy related within the Office of the Secretary.

I think, as Mr. O'Shaugnessy has mentioned earlier, it is our hope that a lot of this research will be done through consortia of operating divisions as well, so that hopefully there will not be large gaps in policy need.

Senator WEICKER. Just by way of interest to the chairman, what is your background relative to these problems, welfare programs, aid to needy children? Aren't you a medical doctor?

Dr. RUBIN. Yes, sir.

Senator WEICKER. What was your previous background on these matters outside of matters dealing with medicine?

Dr. RUBIN. I had no formal training or work in the poverty area. I had some minimal training in economics. I do not have a Ph.D. in economics.

Senator WEICKER. I am not so much interested in that as whatever practical experience you might have in the various types of programs. I can understand where being a doctor would be a valuable background for NIH.

Dr. RUBIN. I think it is important to understand that I have several deputies that work for me. One of my deputy assistant secretaries is a professional economist and has a very distinguished background in these specific areas. He clearly advises me in the area of income security policy.

While I have no formal training in economics or in poverty research per se, I certainly have a background in research and understand the scientific method, how one goes about doing research, and how one goes about interpreting research. In the technical aspects I receive advice not only from my Deputy Assistant Secretary, but also our staff of economists and technicians who are proficient in the field of poverty research.

And, in fact, one can rarely separate the socioeconomic conditions of these populations from their medical problems.

Senator WEICKER. I couldn't agree with you more, Dr. Rubin.

### INFANT MORTALITY RATE

Since we are extolling the nirvana in which the core of this country dwells under the policies of this administration, I would suggest that maybe I was trying to relate to testimony we have had before this committee. Well, let's take prenatal care. Let's come down your alley.

Related to socioeconomic policies of the administration, what do you think about the high infant mortality rate in inner cities in America, since the budgeted money for prenatal care has been cut out by the administration?

Dr. RUBIN. It has been well-documented in studies done in the last several years that with certain prenatal care afforded to people in lower socioeconomic status that they tend to have higher birthweight babies. Clearly that decreases infant mortality substantially.

Senator WEICKER. So what do we do about these low birthweight babies that occur with a high incidence in the poverty area?

Dr. RUBIN. I think clearly there are three things that I think we can do.

No. 1, I think is to make people aware of services that exist. I think the study in the Commonwealth of Massachusetts indicated fairly clearly that a large number of the susceptible population was not aware that these services were available. So we need to do a better job of educating the public.

No. 2, we need to take a better look at ways to increase birthweight. We need to advise expectant mothers of the effects of diet and smoking, on their babies which have demonstrated effects.

And, third, we may need to make these services more convenient for the users. The major provider currently is the maternal child health block grant.

We need to encourage the States to provide these services. And, indeed, my understanding is that evaluations of the maternal and child health block grants show that current service levels for prenatal care are being maintained at the State level.

Senator WEICKER. I have no further questions of Dr. Rubin.

Do you, Senator Proxmire?

Senator PROXMIRE. No.

Senator WEICKER. There will be other questions for response to the record, Doctor.

## OFFICE OF THE INSPECTOR GENERAL

### PREPARED STATEMENT

Mr. KUSSEROW. Mr. Chairman, I have a short statement that we would like to submit for the record.

[The statement follows:]

## STATEMENT OF RICHARD KUSSEROW

I am pleased to appear before you today to discuss the President's FY 1985 budget proposal for the Office of Inspector General, Department of Health and Human Services.

The FY 1985 OIG budget request includes an increase of $3,817,000, chiefly for cost-of-living increases necessary to continue OIG operations at the FY 1984 level of effort. An additional $5,100,000 and 118 positions are included for activities previously funded through the Office of Child Support Enforcement. The request also reflects a reduction of $37,494,000 in FY 1985 associated with the transfer of funding for State Medicaid Fraud Control Units (SMFCU) from the Office of the Inspector General to the Health Care Financing Administration, "Grants to States for Medicaid." The OIG budget request will continue to fund the full range of functions of the Office of Inspector General.

### Redirection of Effort:

Since FY 1982, to meet our overall goal of reducing opportunities for fraud, waste and abuse, the Office of Inspector General has focused on two major objectives:

(1) shifting OIG priorities to be commensurate with allocations of total budgetary resources of the Department, namely, Social Security and Health Care Financing; and

(2) improving OIG management practices to maximize efficiency and effectiveness of operations.

The successful pursuit of these two objectives has proven beneficial in terms of improving the effectiveness of the OIG in thwarting fraud, abuse, and waste; increasing dollar recoveries to the Federal treasury; and expanding OIG productivity without increasing resources.

Our accomplishments for FY 1983, as summarized in our Semiannual Reports, suggests that we are on the right track. The realignment of OIG components to parallel major Departmental programs is relatively complete. Our work in this area is now at the fine-tuning stage to insure maximization of staff resources. This re-deployment involved a massing of resources at points where the risk of loss was highest and where expansion of the use of civil as well as criminal remedies in conjunction with audit and systemic recommendations would assure magnification of our efforts.

Our documented overall savings for FY 1983 was over $1.4 billion, a recovery that represents 4 times the amount recovered in FY 1982, and 9 times that returned in FY 1981. Thus, for each OIG operating dollar in FY 1983, the OIG realized a return to the Government of $20.00 for a cost effective ratio of 20:1

in contrast to the ratio of 4:1 in 1981 and 8:1 in 1982. Based on our current level of productivity achieved in FY 1984, we expect that our cost effectiveness will continue to improve through FY 1985.

For FY 1985, we will continue to focus our audit resources on those program areas in the Department with the largest Federal responsibility: Social Security, Medicare and Medicaid. Projected outlays for these programs during FY 1985 are set at $303.6 billion which is 95% of the Department's total outlays of $318.1 billion. National concern over how these programs will be financed over the short- and long-range supports the need for independent OIG audits which will contribute towards solving program operational problems.

Using the program knowledge we have developed over the years, and with our increased use of advanced computer-assisted audit techniques and microcomputers, we will be undertaking projects and activities geared toward detecting and controlling fraud and abuse within these programs. Also we will seek and recommend ways to improve fiscal controls in each of the benefit payment processes, in trust fund financial management and accounting operations and in overall program administration. Lastly, we will make recommendations for improving management efficiency and overall internal controls.

Similar accomplishments have been realized in our investigative work. Our number of convictions has quadrupled FY 1982 figures, rising from 200 to over 800. Also our investigative activities are resulting in recoveries--through fines, restitutions, savings and settlements--of more than $2 for every $1 spent.

In FY 1985, our Office of Investigations will continue to emphasize prosecution of fraudulent and abusive health care providers. Our investigations will target on high-impact areas, particularly complex organizations in which fraudulent activities are most costly and offer the opportunity for greater monetary recoveries.

A significant number of our FY 1983 convictions can be attributed to our increased emphasis on using computer-assisted investigative techniques to detect defrauders and to organize evidence for prosecutions. Use of computer applications have contributed to over 300 convictions in the last 2 1/2 years, plus millions of dollars in recoveries. The grouping of cases for mass indictment in the various regions has vastly increased acceptance for prosecution and conviction and has attracted public attention, thereby enhancing their deterrent value. A managerial by-product of our increased use of computers has been a trend of increased productivity by the staff. However, the major charge of this office will continue to be identifying processes which give rise to the opportunity for fraud and abuse. The weaknesses will be identified in fraud alerts, summarized in our management implications reports, and analyzed and translated into recommendations for corrective system changes to deny further opportunities to potential wrongdoers.

Since August of last year, we have gone full speed ahead with our Civil Money Penalties program. For FY 1983, that effort has produced close to $2 million in direct returns, offsets and savings through settlements with health care providers who have submitted false claims. Another $2.75 million has been collected so far this fiscal year. Since the law's passage in 1981, staff have produced a series of investigating and interviewing guides, program description handouts as well as briefings for interested parties on the complexities of the statute...all done without budgetary enhancement, through an internal reallocation of resources. Last August, the authority to exclude or otherwise sanction health providers who abuse or defraud Medicare or Medicaid was reassigned to the OIG. In the short period this authority has been with us, we have sanctioned 350 wrongdoers, more than the entire history of this authority going back to its inception in 1972.

Our inspection activities have taken on a two prong approach. During FY 1983, we have issued over 103 reports on system abuses which represents a management commitment to recover or avoid $110 million in cost, identified systemic weaknesses that account for over $40 million in savings, and pursued hundreds of health provider cases involving overpayments of more than 25 million dollars. In addition, this staff is presently simulating hospital conditions in an attempt to detect potential areas of fraud and abuse within the new prospective payment system.

We will continue our efforts to conduct investigations and inspections to identify improper health care provider practices or weaknesses in program policies or their implementation.

Our inspections activity also focuses on identification and prevention of generic causes of fraud, abuse and waste in agency programs, recommends program improvements by conducting brief and timely program evaluations and management analyses of Social Security Administration, Public Health Service, Office of Human Development Services and the Office of the Secretary; and undertakes special studies to identify trends and patterns of fraud and abuse. We also review Departmental regulations and legislative proposals and develop new cost effective proposals for legislation. Last year, staff examined 126 proposed HHS regulatory changes and 184 proposed HHS legislative changes. My office was also responsible for coordinating the development of 18 OIG initiated legislative proposals that are now being considered in the Department's FY 1985 legislative process.

In closing Mr. Chairman, I want to assure you that comprehensive efforts exist and will be on-going to combat fraud, abuse and waste. What I said today, provides only a small sampling of our activities for the past year. More importantly, I believe that these achievements reflect the expectations expressed by Members of this Committee and other Committees since the enactment of Inspector General legislation. I will be pleased to respond to any questions you or other Members of the Committee may have.

## BIOGRAPHY OF RICHARD KUSSEROW

Richard P. Kusserow was nominated as Inspector General of the Department of Health and Human Services by President Reagan in April of 1981 and confirmed by the Senate in June.

As Inspector General of the Department of Health and Human Services, he is charged with the statutory responsibility to ferret out fraud, waste, abuse and inefficiency in the world's largest agency; whose budget of nearly $300 billion represents 38 percent of the Federal budget and by itself would be the largest budget in the world after those of the U.S. Government and the Soviet Union.

Included among the Department's nearly 300 health and entitlement programs are Social Security, Medicare, Medicaid, Aid to Families with Dependent Children, Head Start, Foster Care, Indian Health Service, Native American Programs and Centers for Disease Control.

Under his direction, the staff of 1,400 auditors, inspectors, management analysts and investigators have increased their statistical accomplishments eight-fold. In this last year alone, nearly $1.5 billion in fines, settlements, recoveries and cost avoidances were achieved; along with more than 800 felony convictions.

Kusserow currently serves on the President's Council on Integrity and Efficiency (PCIE). He chairs the Council's Computer Security Project, Health Provider Fraud Committee, Front-End Subcommittee of the Committee on Prevention and co-chairs the Computer Matching Committee.

He earned his bachelor's degree in political science from UCLA, master's degree in Government from California State University at Los Angeles, followed by postgraduate work at Southern Methodist University and John Marshall University schools of law.

Kusserow served in the United States Marine Corps and was discharged as a captain. He was an intelligence officer with the Central Intelligence Agency (CIA) before moving to the Federal Bureau of Investigation (FBI) in 1969.

As an FBI agent, he worked in Pennsylvania, Washington, D.C., and West Virginia before being assigned to Chicago for the 12 years preceding his appointment as Inspector General. A recognized authority on program fraud, white collar and organized crime, he established a number of new investigative squads in the areas of Governmental fraud, public corruption, labor racketeering and organized crime. He acted as the coordinating supervisor for nine squads of agents constituting the Chicago FBI organized crime program.

He is President of the Association of Federal Investigators and an active member of the Society of Former FBI Agents, Federal

Law Enforcement Officers Association, Association of Government Accountants, International Association of Chiefs of Police, American Society of Industrial Security and the American Society for Public Administration. He has lectured widely and authored a number of articles on innovative investigative and management techniques.

### GAO INDIRECT COSTS REPORT

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Mr. Kusserow, as you know, the General Accounting Office recently issued an indirect cost report that was quite critical of your office. The report indicated that over a 5½-year period, the Office of Audit issued indirect cost audit reports on only 47 of an estimated 700 grantees under your jurisdiction and also receiving NIH research funds.

Do you consider this to be adequate oversight?

Mr. KUSSEROW. Absolutely not. I think that is an understatement. We have audit cognizance over 96 percent of the 2,800 colleges and universities receiving Federal funds, but we haven't been doing a very good job in exercising that responsibility all along.

However, the audit universe that relates to research is quite a bit smaller, at about 700 schools, and that is the group to which I believe you are referring. I would also submit that out of these 700 schools, 125 have 90 percent of the research dollars. Therefore, we are talking about a much smaller universe in terms of the dollars associated with research.

But the problem is more fundamental. I think it's the way Government has been doing business with universities. We had gotten ourselves into a situation where we were playing a numbers game with universities, and we were engaging in indirect cost negotiations, and it was a question of how can they hide the money versus can we find the money.

The fundamental issue is whether we can do business better and more efficiently.

One of the overriding problems that we had with universities is their accounting systems. We needed to review them on the front-end side, and this had not been done. Subsequent to my arrival as Inspector General in 1981, we have had a major shift in the way we are conducting our cognizant responsibilities.

This shift has been brought about by the fact that in 1981, I found that about 25 percent of our audit resources were devoted to the university nonprofit area, and that represented less than 2 percent of our Department's money and vulnerability.

In fact, the thing that I found most shocking is that as a result of work in reimbursable gain in the university environment, we were on a narcotic that was causing us to throw more and more resources into this area. It was at the expense of the Social Security Administration, which represents about 70 percent of our Department, and the Health Care

Financing Administration, which now represents some $80 billion in outlays annually. The fact that was even more shocking was that in the 20 years of the audit agency of this Department, both in the Inspector General's Office, as well as in its precursor form in the Comptroller's Office, there never had been an auditor of that office that had ever set foot in any one of the 1,500 district offices of Social Security or any of the six payment centers.

Furthermore, in the Health Care Finance Administration, the second largest component of our Department, we had no organized audit activity relating to the Health Care Program, so we were dependent upon HCFA requests to determine our work. In summary, we felt there ought to be a redirection of audit resources on a priority basis.

And we had to do it in such a way that we would not, at the same time, abandon our responsibilities as the cognizant auditor for 96 percent of all those universities that were out there.

### INDIRECT COSTS

Senator PROXMIRE. Well, I want to discuss that Social Security issue in just a minute, but first let me ask you this. The GAO report also indicated that audit requests made by indirect cost negotiators were honored only 50 percent of the time over a 4½-year period.

What would be your basis for deciding not to honor such a request?

Mr. KUSSEROW. Well, if in our judgment, the request was not unreasonable, nor unnecessary, and was cost effective, and the request could be, in fact, answered by audit, we would honor it. If not, we would not honor it.

Senator PROXMIRE. Does that happen 50 percent of the time?

Mr. KUSSEROW. No; the fact is I think we're more than generous in honoring the requests. In fact, we've recently worked out with the Assistant Secretary for Management and Budget that if there is a manifest need for an audit that we will move ahead on it in every instance.

Senator PROXMIRE. It seems to me that a refusal to conduct a requested audit tends to undercut your negotiators and is very expensive in the long run. It may be penny-wise, but pound foolish.

Mr. KUSSEROW. Actually it's just quite the contrary, Senator. What we have found is that, in terms of return for audit dollar expended, the university environment represents the lowest return of any audit activity that we would have.

Senator PROXMIRE. I'm talking about audits requested by your own negotiator.

They say they've got to have an audit, need an audit for negotiating purposes.

Mr. KUSSEROW. In those cases, an audit would be conducted.

Senator PROXMIRE. Half the time you say a negotiator can't have a requested audit.

Mr. KUSSEROW. Well, any time there's a need for an audit, they will have it. That I will put on the record and maintain.

Senator PROXMIRE. Well, that's your view. But their view, of course, is that they wouldn't request it if they didn't need it.

Mr. KUSSEROW. Well, I think what we have done over the last couple of years is sit down with those folks and work out what should be the criteria for an audit. It's very easy for people to say, "drop it on the auditors and do some sort of an audit."

What we require is a request that specifically outlines what it is that they want us to look at, what grounds they have for doing it, and on what basis, I will then make the judgment as to whether or not we will do it; not the Assistant Secretary for Management and Budget or the indirect costs negotiators.

### SOCIAL SECURITY WORK MEASUREMENT

Senator PROXMIRE. Now, to get to the Social Security issue which you properly raised. I understand you planned to make a study of the Social Security Administration's work measurement system early last year, but you decided to abandon the effort.

Can you tell us why you abandoned the effort?

Mr. KUSSEROW. We're not abandoning the effort. We were delayed in as much as SSA changed their work measurement system before we could begin. One of the problems that we also encountered with the Social Security Administration is 20 years of neglect by our office. We did not even know how to audit that environment because we didn't know how a Social Security district office worked, let alone a regional office or a payment center.

Therefore, the first step in the process required us to survey their operation so that we could know how to go about performing an audit. We did go out and study the operations of the Social Security Administration in its field entities. as well as headquarters and its payment centers.

Based upon that, we were then in a position to be of some use. Otherwise, we were flying blind without any kind of a map or direction.

Senator PROXMIRE. I'm talking about work measurement systems, specifically.

Mr. KUSSEROW. Yes.

Senator PROXMIRE. You're talking about the system generally.

Mr. KUSSEROW. But we could not even design an audit to measure it, because we didn't even know how the district offices worked and SSA was in the process of changing the system.

Senator PROXMIRE. Did you do a preliminary examination of Social Security's work measurement?

Mr. KUSSEROW. We examined the entire process: how the district offices function and what paper they went through and how they measured themselves and everything else. But it was not with any kind of outcome in mind other than educating ourselves so that we would know how to go into the system and study it to actually come up with results.

Senator **Proxmire**. Did your preliminary work indicate the system had substantial defects?

Mr. **Kusserow**. Yes.

Senator **Proxmire**. What were the defects?

Mr. **Kusserow**. I think the defects of the Social Security system were so manifest that they could not be enumerated during the course of this hearing.

Senator **Proxmire**. Would you give us a summary of those defects for the record?

Mr. **Kusserow**. One of the biggest problems they have is the fact that they're operating with antiquated systems which I might add they're in the process now of trying to upgrade. The systems are so antiquated that if somebody's parent were to die who was receiving old age survivor's insurance, it would take on average, four requests on the system before it would actually be corrected.

So that's a very inefficient operation. Four times to try to get it off means that four times it goes through the system before it actually works. So what you have is a paper flow that is not functioning properly.

We also have problems in internal controls. The basic computerized systems that they're working with are antiquated. They have systems built one on top of the other, designed and developed by employees and contractors who used the most exotic software available that nobody else understood. When they died off or moved on, the system could not work without having some sort of manual override.

The end result of that is that there is no audit trail on transaction. That means that a person could take any amount of money out of the system without leaving an evidentiary trail.

### SOCIAL SECURITY SYSTEM UPGRADING

Senator **Proxmire**. Well, this sounds like a real nightmare. It sounds like a relatively modest investment of funds would save the Government a lot of money in the long run.

Mr. **Kusserow**. Absolutely. The fact is we have in process now a $500 million upgrading of the Social Security system that will cure the vast majority of the problems that are there now. Therefore, we are in process of improving the system and developing a better way to deal with the problem. The new systems would, in fact, provide controls on proper processing. Therefore, when a person's parent dies, the family will not have to deal with the constant irritation of Social Security checks continuing to come after they have asked them to be terminated.

The mere magnitude of Social Security makes any adjustment a very, very heavy investment.

Mr. **O'Shaughnessy**. Senator, if I might interrupt here, I'd like to add that management is very, very aware of all of these deficiencies and is working not only with the Inspector General, but Social Security most particularly on the system's modernization plan.

One judgment we're making as we go along here is that we want to pursue a long-term strategy whereby we do a complete overhaul of this system. We do not want to be diverting resources at various points in time to solve smaller problems. We want to overhaul the whole system and be successful in that; and it's a 5-year project.

### WASTE IN SOCIAL SECURITY SYSTEMS

Senator PROXMIRE. Did your preliminary study include any estimate of the potential error in workload count and the effect of such error on staff budget estimates?

Mr. KUSSEROW. No; nothing definitive.

Senator PROXMIRE. OK. Well, it sounds to me as if you're onto something that can be very helpful in cutting Federal costs, literally billions of dollars of waste. I hope you'll give us as much as you can for the record in supplementing what you've told us this morning.

Mr. KUSSEROW. Certainly. I'll be delighted. The fact is I feel very much as if we are in a sellers' market, that everybody wants to buy our product. The question is to get the products out fast enough.

[The information follows:]

### GUIDES DEVELOPED BY OIG

The Office of Inspector General [OIG] designed a study of the Social Security Administration [SSA] field office work measurement system for fiscal year 1983–84. Prior to initiation of a full study, the OIG conducted a quick examination of the system and examined previous analyses and/or evaluations of the system. As a result of these activities, OIG determined that a full-scale study of SSA's work measurement system would be premature. This determination was based on:

The lack of indepth knowledge within the OIG of SSA operations and processes.

The recent completion of a GAO study entitled "Social Security's Field Office Management Can Be Improved and Millions Can Be Saved." Since the issuance of the study, SSA had not had sufficient time to develop a strategy to implement corrective actions to resolve the deficiencies identified by GAO.

The Inspector General decided the more prudent course of action at the time would be to study SSA operations on a program specific basis, prior to conducting a study of the work measurement system. Implementation of this strategy has allowed OIG to learn the complex facets of the SSA operations. The outcome of this effort is a series of guides, which focus on methodologies for examining various aspects of the Social Security programs. The following entitled documents were provided to the committee:

### SOCIAL SECURITY INVESTIGATION GUIDES

These guides trace the development and requirements of various aspects of the Social Security programs. They also give descriptions of successful investigative approaches and examples of cases resulting in successful prosecution. Four of these guides have been issued: supplemental security income fraud; Social Security Disability Insurance Program fraud; Social Security Retirement and Survivors Insurance Program fraud; and Social Security number fraud.

In addition to the Social Security investigations guides, OIG has produced the following materials, copies of which were provided to the committee:

### CIVIL FRAUD GUIDES

The OIG published a general explanation of the civil monetary penalties law and two other investigative guides related to civil investigations.

*Civil Monetary Penalties Law of 1981.*—The booklet describes the law which permits the Inspector General to impose penalties and assessments against medicare and medicaid providers for items or services improperly claimed.

*Investigative guide for civil fraud prosecution.*—This guide describes and illustrates the preferred report format for civil fraud prosecutions.

*Discovery and disclosure of assets and financial information.*—This guide presents ways to discover and determine the value of assets which is a crucial aspect to civil prosecution.

### COMPUTER APPLICATIONS

The Office of Audit has developed a series of computer applications which may be used to develop supporting evidence for prosecution or for recommending actions that combat fraud, waste, and abuse. After proving successful, the applications were cataloged and published in three volumes: Volume I—Computer applications in health provider fraud and abuse; volume II—Computer applications in income maintenance programs; and volume III—Computer applications in other Federal and State programs.

Most of the applications inventoried in these compendia contain multiple programs for sorting, extracting, and analyzing data and are available for use by Federal, State, and local governments.

### HEALTH CARE PROVIDERS—TECHNICAL ASSISTANCE SERIES

These investigative guides describe the most prevalent kinds of fraud and abuse encountered in various segments of the health care industry. Thus far three of these guides have been written and distributed: Nursing home investigative guide; dental investigative guide; and pharmacy investigative guide.

A fourth health care investigation manual, "Laboratory Investigative Guide," will be distributed shortly.

### COMPUTER-RELATED FRAUD

In 1983 the Inspector General published the findings of a survey of Government agencies about known cases of computer-related fraud and abuse. The survey was conducted under the aegis of the President's Council on Integrity and Efficiency [PCIE] and covered the period January 1978 to March 1982. The four major findings, which were published in the report "Computer-Related Fraud and Abuse in Government Agencies," were as follows:

The extent of computer-related fraud is unknown, but 172 cases were reported.

The cases primarily involved theft of cash or diversion of assets.

Most perpetrators were Federal employees in nonsupervisory positions.

The prevalence of accidental discovery implies weakness in controls.

### SOCIAL SECURITY SYSTEMS SAVINGS

Senator PROXMIRE. Can you give us any notion of how much can be saved here?

Mr. KUSSEROW. Well, I will say that in the 2 years from 1981 to 1983, the overall results from our office on a dollarwise basis increased 800 percent. It went from $165 million to $1.4 billion last year.

### OIG ACCOMPLISHMENTS

Senator PROXMIRE. It went from $165 million to $1.4 billion what?

Mr. KUSSEROW. Those are savings, recoveries, fines, penalties, assessments. They are a total dollar range of things that come out of our office from the various components.

Senator PROXMIRE. That's not just savings from the Social Security Administration, though. That covers the whole Department.

Mr. KUSSEROW. That's the whole Department, yes. A large portion of that is out of the Social Security Administration.

In the first 6 months of this year, we have already exceeded all of last year's total of $1.4 billion, in just the Social Security Administration alone. We now have been planting the seeds and working in the fields. Now, we are beginning to get some harvest and it will continue in the foreseeable future to improve when it comes to getting results.

Senator PROXMIRE. Thank you.

## COUNTERFIET SOCIAL SECURITY CARDS

Senator WEICKER. What can you tell us about your investigation into counterfeit Social Security cards?

Mr. KUSSEROW. One of the largest problems that we have in the Federal Government is with the Social Security identifier. The Social Security Act of 1936 clearly states that the Social Security number was not to be an identifier, and yet it has in large measure become the de facto universal identifier in the United States.

It is used for bank accounts. It is used for IRS returns. It is used for drivers' licenses. It is used for program eligibility. It is being used for virtually everything in the commercial credit community.

As its universality as an identifier has been growing, there have been attending problems with its use. The system was not set up to protect it against misuse because it was not to be an identifier. It has become very vulnerable to misuse and fraud.

Consequently what we have observed nationwide has been the fraudulent obtaining of Social Security account numbers as well as the manufacturing of counterfeit Social Security cards. We find that undocumented aliens from almost any land are using either a fraudulently obtained Social Security account number or a fabricated Social Security account number to do a lot of improper business.

One misuse might be to obtain a job when they're not authorized to be working in this country as a result of being either undocumented or on a visa that would not permit employment. Or we may find use of a fabricated Social Security card in order to obtain program benefits.

As an example, in Texas 2 years ago, there seemed to be a lot of people who were using Social Security numbers to obtain program benefits when, in fact, the Social Security numbers being used had not yet been issued. Our advanced techniques staff developed a program that would identify all Social Security accounts numbers within a data base that have not yet been issued.

In a data base of 2 million AFDC and food stamp records we came up with a very tiny portion that were fraudulent, only 5,100. But that meant 5,100 people were receiving monthly benefits off a Social Security card with numbers that had not been issued and, therefore, they were not entitled to those benefits.

In closer examination, we found that one-third of them were really error, transposed numbers. But, the other two-thirds were not entitled to those benefits. When we called them up for redetermination, they would say "Thank you very much, I don't need the program benefit anymore," or they were people who could not be found.

Therefore, two-thirds of what we found was clearly in the fraud and abuse area.

In California, in San Francisco, by itself we took a more advanced form of that program that would say not only this Social Security card number has not been issued, but it's an inappropriate number for somebody with the characteristics that were claimed. We found there were 4,700 people that were obtaining program benefits, primarily welfare benefits, using a nonexistent or inappropriate Social Security number. So we certainly feel that we have a large amount of evidence to suggest there is a lot of fraud and abuse in this area.

### SOCIAL SECURITY CARD FRAUD

Senator WEICKER. Let me ask you one question. How do you obtain benefits from a nonexistent number? I don't understand that. Wouldn't that be picked up?

Mr. KUSSEROW. No; unfortunately, it's not. We have what we call Project Clean Data which is now working with 70 different jurisdictions at high levels of Government to try to move on the front-end side, but let's take that case down in Texas.

By all rights, we'd expect with the high technology that exists in Government today at all levels that somebody who we would expect anyone who was to walk into a district or into a program office and talk to a caseworker and say, "I have a need," present a bogus Social Security number that, in fact, if that number were not real or did not belong to that individual they would catch it.

In fact, indeed, that is not the case.

Any program that you devise to surface inappropriate data in a data base can be put on the front-end side and this is what we're working with. What we should have, of course, is a situation that when that caseworker takes that bad number and turns around to enter it into the little CRT thing that they have in front of them, and it's an inappropriate number a flag should jump and say "Tilt" so the person can turn around and make sure that they didn't miscopy the number into the system; and, if they didn't, then turn to the individual while they're still there, before they got one dollar out of the program, and say, "Please, could I see that Social Security card?", and then try to question it up front.

This is where we're moving, but this is not what is going on right now particularly in the States where you have 50 different States operating a multiplicity of programs. So what we're doing is offering our technology and offering our resources to help them do just that.

Another area where we have had a lot of problems with inappropriate data has been a situation nationwide where we have looked at undocumented aliens that have had phony Social Security cards confiscated from them when they were deported. What we have found is interesting.

For example in the Denver area, in monitoring where they had Social Security numbers we would check unemployment compensation 30 days later and we found that 7 percent of the people that were deported with these kind of numbers were getting unemployment compensation. So once again we need front-end controls to avoid that, and that's what we're moving with.

But inasmuch as most of the benefit programs have Federal funds involved in them, they are State administered, which means that we have to go out to 50 jurisdictions with a multiplicity of agencies to educate them and this is what we're doing.

### COUNTERFEIT SOCIAL SECURITY CARDS

Senator WEICKER. Do you feel you're in a position to extrapolate from various samples that you've taken as to what's out there in America in terms of——

Mr. KUSSEROW. This particular problem?

Senator WEICKER [continuing]. Bad cards? Whichever way they're bad, either somebody else's or nonexistent numbers. Do you have any ideas?

Mr. KUSSEROW. Yes, I do. In fact, Mr. Chairman, I'd like to submit a report to you on a study that we did on false identification which dealt with the problem in part and within 60 to 90 days, we will have more definitive information on this.

The difficulty that we have found though, in summary, with regard to the Social Security identifier being misused is that in many cases the misuse does not translate to direct program damage. For example in our Department, if you have an undocumented alien using a phony Social Security card number to get work, they're contributing to Social Security but it's unlikely they'll be drawing against it.

So, in that case, the Social Security Administration might benefit from the illegal, improper use of the Social Security identifier.

Senator WEICKER. Any idea, can you just give me an idea of what the round numbers are we're talking about?

Mr. KUSSEROW. We cannot show in Federal programs a whole lot of direct damage that's the result of phony Social Security cards. We're beginning to get some data to show that there is an effect, and that's what I hope to come up with.

Where the real effect is, quite frankly, is with regard to credit card transactions in the private sector because ultimately they suffer more damage than to Government programs.

Senator WEICKER. What you're saying to me is that I could go into a Social Security office with a totally manufactured number, apply for benefits and the checks will start?

Mr. KUSSEROW. No; the Social Security offices would catch it. But if you were to go apply for food stamps, they wouldn't necessarily catch it. If you were to apply for AFDC, it's unlikely they would catch it. If you were to apply for energy assistance or housing assistance, it's unlikely that they would catch it.

The Social Security Administration would, in fact, catch it for any of the Social Security programs. SSI, they'd catch it. Disability insurance, they'd catch it. The Black Lung Program, they'd catch it.

But with regard to the State-administered programs, no.

Senator WEICKER. But you say that there is an effort to integrate. There is or there is not, so it can be stopped?

Mr. KUSSEROW. Well, we're working on it. The fact is that, yes, I think this is a problem that we can get under control and I think that we're going a long way to doing it.

I'm expending some effort and resources outside of my Department to assist nine pilot States on how to use our software to be able to capture that information. We're doing that because we think that the taxpayers are going to benefit enormously as a result of it. This is an area where we are going to make a lot of progress, and we have an ongoing campaign.

As I say, I'm having data pulled together and I'd be delighted, as soon as I get it pulled together, to give you a full status report as to how that's working and where we're going, what results are coming from it.

Senator WEICKER. I have further questions for response to the record.

Mr. KUSSEROW. Thank you, Mr. Chairman.

## OFFICE FOR CIVIL RIGHTS

Senator WEICKER. We have civil rights next up at bat.

Your budget justification indicates a decline of 549 complaints. That's a 33-percent reduction over the 1981 levels.

Why are the complaints declining?

Ms. DOTSON. Well, I'm unable to give a precise reason for the decline. I certainly wouldn't go so far as to say that the reasons for which we exist have disappeared.

I do feel, however, that many of our beneficiary groups, our constituency, are not entirely aware of the fact that we're there to address their concerns. Toward that end, we've been trying to make a concerted effort to deal directly with our constituency groups, that is, the handicapped and minorities, to make sure that they understand that the Office for Civil Rights exists to deal with their concerns.

## BUDGET REDUCTION

Senator WEICKER. You also indicate that you expect to receive the same number of complaints in fiscal year 1985, yet you're requesting a reduction of almost $1.1 million budget authority and staffing reductions of 50 positions.

How is that?

Ms. DOTSON. The reduction is based on the historic decline in complaints since 1981 and increases in work productivity and efficiency.

Senator WEICKER. Of course, as I'm saying, you expect to see the same number of complaints, but you're reducing your staff and budget.

Ms. DOTSON. I believe that we are going to be able to handle that because we are increasing our productivity.

### CIVIL RIGHTS REVIEWS

Senator WEICKER. How many investigations, just out of curiosity, do you initiate; not by way of complaints, but initiate?

Ms. DOTSON. We don't initiate investigations, usually. We initiate compliance reviews and a small percentage of compliance reviews might result in investigations. I would be happy to supply those figures for you for the record.

[The information follows:]

During fiscal year 1983, OCR initiated 130 compliance reviews and 437 project reviews.

### EXTENT OF DISCRIMINATION

Senator WEICKER. My problem is you cut your legal staff last year 25 percent, cutting your compliance staff this year 20 percent. You've already indicated, as I said, a 33-percent reduction since 1981 of 549. Complaints are going down.

I sort of get the impression that maybe you people feel if you go away the problem goes away, will be gone.

Ms. DOTSON. No; I don't feel that way at all.

Senator WEICKER. It seems to me that in the laws passed by the Congress and those initiated by other administrations there's even more civil rights work to do, not less, today than there was 10 years ago. I can think of matters that pertain not just to race, but to physical condition, sex, et cetera, whereas I think in the main, several decades ago, the problems were mainly associated with race. I don't think those have gone away either; but, as I say, they've been added to.

I don't understand quite what's going on over there in your Department.

Mr. O'Shaughnessy?

### WORKLOAD DECLINE

Mr. O'SHAUGHNESSY. Yes; if I might just present some figures.

The 1985 complaint workload expected is approximately 32 percent below the level of 1981; 1,155 new complaints are estimated, the same as in 1984; but that's down from 1,704 new complaints received in 1981. The reduction in staff that's being outlined is a 10-percent reduction from the 1984 level, but it is less than the continual decrease in the workload.

It is true that we expect the complaint workload to be level from 1984 to 1985.

### SCOPE OF JURISDICTION

Senator WEICKER. What specifically is the constituency of your office as to who you're supposed to be serving?

Ms. DOTSON. Persons protected under title VI of the Civil Rights Act of 1964 which applies to race, color, and national origin; the handicapped, who receive protection under section 504 of the Rehabilitation Act of 1973; the aged under the Older Americans Act; and additional responsibilities for community service assurance under the Hill-Burton Act.

### INSTITUTIONALIZED PERSONS

Senator WEICKER. How does this jibe with the investigations of my subcommittee on the handicapped where we've uncovered the grossest abuses in mental institutions in this country and where I have had to use my own staff in an investigatory sense?

What do you initiate in that area, or have you done any work on that sort of thing?

Ms. DOTSON. I'm unaware of any specific Office for Civil Rights cases which relate to mental institutions or hospitals.

Senator WEICKER. Unaware?

Ms. DOTSON. Yes, sir.

Mr. O'SHAUGHNESSY. Mr. Chairman, if I might address this subject. The States have the primary responsibility for inspecting these facilities.

Senator WEICKER. We've been all through that and the States aren't going ahead and shouldering that responsibility. That's why we got into it.

Mr. O'SHAUGHNESSY. That's correct. HHS has a backup staff for overriding the States, as necessary, to go in and visit those nursing homes. That staff is connected to ours within title XVIII and title XIX reviews; our construction facilities' engineering people conduct the physical review, and will continue this work through the Public Health Service.

We have been working with your staff in terms of going out and looking at nursing homes.

Senator WEICKER. I'm well aware of the fact that the Secretary has been very helpful in working with my staff on abuses since 6 months ago, or something. On the other hand, obviously this is the time if, indeed, abuses have been unearthed—and it's my understanding they have; we're having hearings on this very shortly—to translate what it is that we've found and what it's doing to the budget process.

I'm saying that really, as I understand it, your principal entry into this scenario is by virtue of medicaid. Is that correct? And the administration of medicaid.

Mr. O'SHAUGHNESSY. That's correct.

### OCR INTEREST

Senator WEICKER. How does the Office for Civil Rights mesh into this? It would seem to me that they would be an appropriate ongoing arm to assist in terms of setting up the standards of nursing homes, mental institutions, et cetera, as required by law.

This is my concern. At a time when a reduction is being requested, both in moneys and personnel.

Mr. O'SHAUGHNESSY. Senator, what I've addressed has to do with the departmental review of conditions of participation in the medicaid and medicare programs and compliance with those conditions. These reviews, as you know, focused largely on physical plant and equipment and facilities.

I am personally not conversant with the review of these homes by way of the civil rights of the individuals. We can look into that and provide information for you.

[The information follows:]

Since fiscal year 1980, OCR has processed 319 complaints alleging race, national origin, or handicap discrimination in mental health programs. Forty-two percent of the complaints were employment-related, such as alleged discriminatory hiring or firing practices; 24 percent alleged discrimination in the quality or level of services provided; 12 percent dealt with accessibility or availability of services, such as cases where facilities were not physically accessible to sensory or mobility impaired persons; and 10 percent of the complaints concerned admissions policies or practices which allegedly had the effect of excluding or screening out certain beneficiaries. During this same period of time, OCR also conducted 45 compliance reviews focusing primarily on differential treatment and accessibility or availability of services in mental health programs.

## CIVIL RIGHTS OF INSTITUTIONALIZED PERSONS

Senator WEICKER. Do you have a responsibility for the civil rights of institutionalized persons?

Ms. DOTSON. I'm not sure that we do. Of the institutionalized persons?

Our responsibilities arise out of the jurisdiction——

Senator WEICKER. I'll tell you what I think we better do here. I think we better have the staff consult on this specific issue as a part of our ongoing cooperation with the Secretary.

It seems to me that, yes, there is a responsibility here——

Mr. O'SHAUGHNESSY. I agree with you, Senator.

Senator WEICKER [continuing]. And an opportunity here, and rather than belabor it since we're already working on it together, let's put our heads together and see what we can do.

Mr. O'SHAUGHNESSY. We'd be pleased to do that, Senator.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record.

Mr. O'SHAUGHNESSY. We will be happy to provide answers to any questions you may have.

Senator WEICKER. Any further statements that you have will be accepted for inclusion into the record in their entirety and there will be further questions from the committee.

Mr. O'SHAUGHNESSY. Thank you very much, Senator.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## GENERAL DEPARTMENTAL MANAGEMENT

### REVIEW OF NIH RESOURCES

Question: Do you consider it your responsibility to see that the views and estimates of NIH and the other agencies within the Department are brought to the Secretary's attention before she goes to the White House?

Answer: Yes, I do. During the FY 1985 budget formulation cycle, I was appointed Assistant Secretary for Management and Budget after the Secretary's meeting with White House staff. However, our internal budget process did afford the Secretary the opportunity to consider the issues of the Assistant Secretary for Health and the Director of NIH regarding budget levels. In addition, she is regularly kept abreast of all budgetary issues which affect the agencies of the Department. We will certainly continue this feature of our budget formulation process during the FY 1986 cycle.

### DEPARTMENTAL REVIEW

Question: I understand that your FY 1985 request is based upon the Grace Commission's recommendations and subsequent departmental reviews concerning the size and structure of the Office of the Secretary. When were the Departmental reviews begun and how long did they take? Please describe the review process. When were the final recommendations presented to the Secretary? How long did it take to receive her decision? Did Messers. Stockman and Meese approve the Department's recommendations as presented? If they made changes in the recommendations, what were those changes?

Answer: The written report by the President's Private Sector Survey on Cost Control was the starting point for our review of Office of the Secretary staffing. Early last summer, Secretary Heckler appointed a senior management review team, which included career staff, to carefully review the Grace Report and to recommend specific staff levels and organizational changes to streamline operations and make the Office of the Secretary operate more efficiently. That team presented staff division by staff division recommendations to the Secretary in early August. At that time, Secretary Heckler made broad policy and conceptual decisions to reduce Office of the Secretary staff by approximately 1,200 and, in doing so, to rely heavily on attrition and transfers in order to minimize the number of employees separated. She also decided to avoid any major disruptive reorganizations.

Detailed plans and cost estimates were not developed when we submitted our budget request to the Office of Management and Budget on September 15, 1983. Some, but not all of these details were developed and agreed upon during the period of OMB review and passback. The aggregate agreed-upon resource levels were incorporated in the President's Budget released on February 1, 1984. Between early February and mid-March of this year, the senior management review team finalized details of the reduction plan and presented a specific plan to the Secretary which she approved in mid-March.

The final plan was announced on March 19 through a memorandum from Chief-of-Staff George Siguler to Office of the Secretary Staff Divisions.

## OS REORGANIZATION

Question: Are your plans for reorganization in the Office of the Secretary complete as represented? If not, what additional changes are you considering?

Answer: Our FY 1985 budget fully carries out the plan outlined in the March 19 memorandum from the Chief of Staff. We feel this plan balances the need to make substantial reductions in the FY 1985 budget with the Secretary's goal of minimizing adverse effects (such as separation from the workforce) on individual employees. In short, we believe we are doing the most we can in FY 1984 and FY 1985 without major disruptive reorganizations. However, in developing the FY 1986 budget, we will continue to look for possible actions which will further streamline the Office of the Secretary, eliminate duplication of effort and, in general, reduce overhead in the Department.

## STAFFING REDUCTIONS

Question: You are planning to reduce the workforce of the Office of the Secretary by 1,264 FTEs. Is this number now firm? Do you project any additional reductions in FTE within the next two years?

Answer: Yes, that number is firm. The 1,264 FTE reduction represents the decrease from the FY 1983 FTE ceiling to our FY 1985 request level for the General Departmental Management, Policy Research, Office for Civil Rights and Working Capital Fund appropriation accounts. We have not yet formulated our plans for FY 1986 and, therefore, cannot make any definitive statement regarding FY 1986 FTE levels. Nonetheless, I can assure you that we will continue to seek ways to reduce duplication of effort between the Office of the Secretary and the Department's Operating Divisions.

## GRACE COMMISSION RECOMMENDATIONS

Question: The Grace Commission recommended reducing the Office of the Secretary by 1,674 positions. Are you planning to achieve the recommended total of 1,674 at a later date?

Answer: We have not proposed to match the 1,674 reduction figure included in the Grace Commission's recommendations. That figure represents a composite of positions, FTEs and on-board personnel. About half of the difference between our plan and the Grace Commission's recommendations is a consequence of different approaches to measuring the reduction.

In addition, the Grace Commission made two reorganization proposals we chose not to implement. One proposal was the folding of most of the Office for Civil Rights into the Office of the General Counsel and the elimination of 156 of the remaining staff. The other proposal not implemented was the merger of the Immediate Office of the Secretary with the Offices of Legislation and Planning and Evaluation. We will look for other opportunities to make responsible reductions in overhead support as we review FY 1986 and future years' budgets.

## INFORMATION REQUESTS

Question: When this committee requests information from the Department regarding appropriation items, whose responsibility is it to assure we get a timely response?

Answer: It is my responsibility as Assistant Secretary for Management and Budget to insure that the Appropriations Committees receive timely responses to Appropriations Committee requests. The Office of Budget will continue to coordinate and prepare all the materials sought by the committees.

## ADMINISTRATION OF TITLE IV FUNDS

Question: Why did it take four months for the Secretary to respond to Senator Proxmire's and my letter regarding the administration of funds for Older Americans?

Answer: The Committee's directives regarding the administration of Title IV funds for Older Americans were considered by the Department as part of a larger package of overall report language directives affecting all Departmental programs. The range of areas under consideration was very broad, and included directives related to Medicaid, Family Planning, Refugees, staffing in the Offices of Human Development Services and Community Services, and other areas. As a result, input was sought from Offices across the Department, and each item was given thorough and careful review and consideration--a necessary, but very time-consuming process. Only after decisions had been reached on all of the items in the package was the Department in a position to formally respond to the various letters of inquiry which had been sent reqarding individual items.

## ASSISTANCE TO CONGRESS

Question: At what point do you assume responsibility for assuring service to the Congress--including the staff of the Appropriations Committee?

Answer: The Committees and their staffs will continue to receive all materials the Office of Budget has traditionally provided. Your staff and mine have discussed this matter, and we see no barriers to providing timely and effective assistance to the Subcommittee.

## FACILITIES ENGINEERING

Question: The Office of Facilities Engineering was established in 1970 to consolidate offices spread throughout the Department. Now you appear to be decentralizing the Office all over again. Why?

Answer: The justification and rationale for a centralized Office of Facilities Engineering (OFE) no longer exists. OFE was established when the Department was involved in a broad spectrum of direct Federal and Federally assisted construction, including Hill-Burton Act hospital construction and work for the Office of Education. Much of the workload has declined in the years since the consolidation.

Since that time, the Department of Education was separated from the former Department of Health, Education and Welfare, Hill-Burton program work has steadily declined and our direct Federal Construction program funding levels have also decreased. The majority (68%) of our Federally Assisted work effort is expended in support of the Department of Housing and Urban Development's Section 242 program which, programatically, is administered by the Public Health Service.

Similarly, the remaining direct Federal construction work effort directly supports the Public Health Service program activities, primarily the Indian Health Service.

The need for maintaining a centralized services organization in the Office of the Secretary can no longer be justified under current circumstances. For these reasons, the decision was made to retain a small staff in the Office of the Secretary to manage cross-cutting activities and to place the remaining activity responsibility with the Public Health Service who has programmatic responsibility for the majority of the remaining programs.

## SAFETY INSPECTIONS

Question: This office is responsible for conducting safety inspections in institutions receiving Medicare and Medicaid funds. Can you assure this Subcommittee that these inspections will continue in a timely manner and be performed by qualified personnel.

Answer: The current level of technical support for life-safety inspections for the Medicare and Medicaid Programs amounts to six workyears. Position ceiling in this amount is being transferred to the Public Health Service for the specific purpose of continuing this program under an Interagency agreement between the Public Health Service (PHS) and Health Care Financing Administration (HCFA). We do not anticipate any change in the level or quality of these inspections as a result of this transfer.

Question: Who will perform these inspections now?

Answer: The Public Health Service (PHS) will perform these services under a reimbursable agreement with the Health Care Financing Administration. PHS has a comprehensive facilities engineering operation and, with the resources being provided from the Regional Operations for Facilities Engineering and Construction (the regional component of the Office of Facilities Engineering) for the function, PHS will be able to provide all inspection services necessary.

## ENGINEERING SERVICES

Question: Engineering services were provided to other Federal agencies (inspection of HUD-financed facilities, as an example). Will these services continue to be provided? If so, at whose expense?

Answer: We are currently providing services to other Federal agencies outside the Department on a reimbursable basis. The status of each of these arrangements is being re-evaluated. In the case of the HUD Section 242 Hospital Construction Program, HHS provides 22 staff workyears from within our Departmental Management ceiling for professional architectural engineering services. HUD reimburses the Department for the related costs of these services. The Department of Education (DEd) has provided staff (15 FTE) and reimbursed actual cost associated with services; however, the work effort is more nearly 24 FTE in FY 1984.

We are holding ongoing discussions with HUD to arrive at a more equitable arrangement for reimbursement of both Departmental FTE and cost. A final decision on the exact level of services cannot be made pending resolution of these discussions. We are holding similar discussions with DEd to determine whether they will continue use of HHS services under the current arrangement or undertake the activity under their own auspices. Finally, miscellaneous functions provided to the Department of Interior and Appalachian Regional Commission will be handled by the Public Health Service from workyear ceiling and resources being transferred to that organization. We will continue to provide services for all these activities under current memoranda of agreement pending resolution of evaluations and negotiations currently in progress.

## TRANSFERS TO THE OPERATING DIVISIONS

Question: You have indicated that 530 Office of the Secretary employees have already been transferred to the Operating Divisions. When did this occur?

Answer: The figure of 530 refers to the annualized full-time equivalent (FTE) employment ceiling associated with the transfers to the Operating Divisions that are included in the FY 1985 budget request for General Departmental Management. As a cumulative measure of total workyears expended during a fiscal year, FTE does not equate to the number of employees transferred. Rather, the 530 FTE represents the employment ceiling allowances included in FY 1985 Operating Divisions' budgets for staff previously charged to the Office of the Secretary.

The 530 "transfers" are presented as already accomplished only in the context of a plan to achieve a 1,264 FTE reduction in OS from FY 1983 to FY 1985. In this context, the realignments of certain support staff being undertaken in FY 1984 will have the effect of allowing OS to enter FY 1985 with reduced employment equivalent to 530 FTE below the FY 1983 ceiling level.

Of the 530 FTE savings reflected in the FY 1985 GDM budget request, 447 were transferred on October 1, 1983 and 83 will be transferred in the second half of FY 1984.

Question: I would like you to provide for the record an exact accounting of the transfers, including the number of employees transferred to each division, the source of payroll funding for each employee in FY 1984 and funding plans for FY 1985, as well as the rationale for each transfer.

Answer: Effective October 1, 1983, 447 FTE were transferred to the Social Security Administration. Payroll obligations for these employees are being met from the General Departmental Management appropriation in FY 1984. Funding for these positions is included in the Social Security Administration, "Limitation on Administrative Expenses" account in the FY 1985 budget request. The transfer involves only FTE allowances for staff engaged in supporting Social Security programs virtually all of the time. Of the total 447 FTE, 260 FTE are associated with processing disability litigation, and 187 FTE are engaged in providing basic personnel administration at SSA Program Centers and Data Operating Centers.

During the second half of FY 1984, 83 FTE will be transferred to the Public Health Service. Payroll obligations for these employees are being met from the General Departmental Management appropriation in FY 1984. In the FY 1985 budget request, funding for these positions is included in the Public Health Service, "Service and Supply Fund." The transfer consists of 79 FTE performing facilities engineering and construction functions (primarily for the Indian Health Service) and 4 FTE providing advisory committee management services.

In each case, the transfers simply align resources with the programs to which service is provided exclusively.

Question: Also, please explain how you were able to transfer employees to another operating division without transferring funds for payroll expenses.

Answer: Under 5 U.S.C. 301, the Secretary has broad authority over the "distribution and performance" of the Department's business. The transfers of FTE to the Operating Divisions are actually adjustments of the relative employment ceilings used within the Executive departments to control staffing levels. The transfers are reflected in the FY 1985 budget estimates, but do not require transfers among FY 1984 appropriations because the funds continue to be used for their original purpose.

## SPACE AND ADMINISTRATIVE SERVICES

Question: I see that you are requesting increases for Standard Level User Charges, Other Rents and Supplies and Administrative Cost increases totaling in excess of $5.2 million. One would think that fewer employees would require fewer square feet, fewer supplies and fewer administrative services. Please explain the reason for the increases.

Answer: The sum of $5,256,000 is the amount our budget would have gone up due to inflationary pressures if we did not consolidate space or reduce administrative services. This reflects a 27 percent increase in Standard Level User Charge rates over our 1984 level and an estimated 4.5 percent inflation rate in all other areas. These increases are displayed on page 4 of our FY 1985 Budget Justification. The $5,256,000 is offset by a decrease of $2,019,000 in Standard Level User Charges due to space consolidation and $2,224,000 in other rent, supplies and administrative costs related to the staffing reductions for a net increase of only $1,013,000. These offsets are displayed on page 5 of our Justification in the Summary of Changes section.

## CONTRACTUAL SERVICES

Question: The Department has indicated that it will increase the amount of contractual services used by the Assistant Secretary for Personnel Administration for "investigative functions."

Please describe these functions and explain why you are contracting them out.

Answer: The EEO Complaint Investigations function receives and determines acceptance or rejection of EEO formal complaints; conducts investigations and prepares and provides investigation reports to DHHS components.

Over the past several years we have been awarding contracts for EEO investigations to augment our in-house staff. It was determined through an analysis of the in-house cost that it is more cost effective to use contractual services for EEO investigations. The reason we are proposing to contract out this work is that we believe we can get the job done at far less cost to the government without any decrease in the quality of the work product.

Three in-house investigators will be retained to provide administrative support for the contractual services and to conduct critical investigations.

## ADMINISTRATIVE PROJECTS

Question: You are indicating an almost $4 million reduction in ongoing administrative projects and activities. How many projects will be affected?

Answer: The reduction includes decreases in five separate project areas.

Question: For the record, please identify these projects and state how they will be affected.

Answer: The $3,991,000 decrease is distributed among Departmental Management projects and activities as follows:

- $1,661,000 reflects a reduction in costs for the Payment Management System (PMS). We hope to complete on-time costs for final conversion and tying of PMS into the Treasury Financial Communication System in FY 1984.
- $1,484,000 represents a reduction in funding for the Standard Accounting System (SAS). Of this amount, $600,000 was intended for new special project costs to extend the SAS beyond the Office of the Secretary and Human Development Services. The $884,000 is a reduction in ongoing administrative costs made unnecessary by the advent of the Uniform Accounting System.
- The remainder covers a number of decreases in administrative projects such as $357,000 for the Facilities Management System. The facilities engineering activity is being transferred to the Public Health Services, making most of this activity unnecessary. The remaining decreases include reductions associated with converting the OS data processing workload to more efficient computers in the Public Health Service, and reduced development costs for the Departmental Contract Information System.

Question: How will this reduction affect the employees involved with these projects, and how many employees will be separated or transferred as a result of these decisions?

Answer: These reductions do not involve separations or transfers of personnel. The costs which are planned to be decreased are principally in the areas of contracts and telecommunications. Staff effort associated with these projects will be reassigned to ongoing work.

## ADP EQUIPMENT

Question: You indicated in your justification that you will be consolidating ADP functions or making use of ADP equipment located elsewhere in the Department. Why are you requesting an additional $1 million for ADP equipment?

Answer: The consolidation of ADP services is separate from the proposed $1 million increase for equipment purchases. We are proposing to transfer Office of the Secretary (OS) computer operations from the outmoded OS Division of Data Processing (DDP) mainframe computer to more modern and efficient Public Health Service computers. The FY 1985 budget assumes $2.0 million in savings resulting from lower data processing charges under the more efficient PHS computers. We are also simultaneously proposing to upgrade the automation capacity of the Department's Servicing Personnel Offices (SPOs). This upgrade will permit the Department to complete rote personnel processing actions more efficiently than we do now.

Regarding the consolidation, the OS data processing workload is chiefly comprised of processing the payroll for the Department's 140,000 employees. This kind of large batch processing can be done more economically with the modern PHS computer and it is for that activity that we have assumed $2.0 million in lower processing costs in our budget request.

Separate from this $2.0 million reduction, our plan to use more modern terminals in the Department's SPOs will improve the efficiency of processing personnel actions. We hope that over time, the efficiencies gained through personnel office automation will reduce the need for continuing the current number of personnel specialists and other employees throughout the Department.

## PROMOTIONS

Question: In light of the reduction in staffing levels, please explain your request for over $700,000 for promotions.

Answer: We estimate that salary costs will increase by just over $700,000 in FY 1985 because of the effect of within-grade or longevity pay increases and because of career ladder grade promotions. Within-grade increases are calculated at 3% for each step increase. We anticipate that one half of the General Schedule (GS) employee will receive these increases in FY 1985. Career Ladder promotions are offered in some job classification series from the entry to the journeyman level under regulations published by the Office of Personnel Management. By law and regulations, within-grade increases and career ladder promotions will continue even at reduced staffing levels.

## POLITICAL APPOINTEES

Question: I am curious as to whether your reduction in workforce will affect any political appointees. Provide a list of the number of political appointees and Schedule C's working in the Office of the Secretary for FY 1982, 1983, 1984 and plans for 1985.

Answer: The following chart identifies the number of political appointees and Schedule C appointments in the specified years:

| | Political Appointees | SES Non-Career Appointments | Schedule C Appointments | Total |
|---|---|---|---|---|
| FY 1981 | 12 | 27 | 92 | 131 |
| FY 1982 | 14 | 31 | 87 | 132 |
| FY 1983 | 12 | 33 | 72 | 117 |
| as of 04/27/84 | 10 | 33 | 69 | 112 |

We expect that the FY 1985 level will be in line with past years' experience.

## OUTPLACEMENT EFFORTS

Question: It is my understanding that in the past three fiscal years, approximately 5,000 employees have been separated involuntarily from the Department. Have you made any attempt to learn what has happened to these employees? If not, how can you be sure that your reduction-in-force procedures, such as outplacement, are adequate?

Answer: Our experience has demonstrated that our most successful outplacement efforts took place before employees were separated. We have placed into other parts of the Department, other Federal agencies and the private sector, approximately 2,000 employees who otherwise would have been separated.

Since December 1981, approximately 3,200 not 5,000, employees have been involuntarily separated from the Department under reduction-in-force procedures. Approximately 1,800 of these were hired by State or private organizations which took over the Public Health Service hospital facilities that were closed. In addition, approximately 300 employees were rehired into positions in the Department from our reemployment priority lists. Employees remain on our reemployment priority lists for two years. During that time, we continue our efforts to assist them, including counseling and referral to positions in the Department and in other Federal agencies.

## SEPARATION COSTS

Question: Personnel costs related to separations were $1.9 million in FY 1984 and will be $3.6 million in FY 1985. In each of these years: how many of these separations were involuntary due to RIFs. Please describe how these separation costs in FY 1985 totaling over $3.6 million will be used.

Answer: Separations due to the reduction-in-force are planned to occur on September 1, 1984. We do not propose any involuntary separations during FY 1985. Our total cost in FY 1985 for all benefit and other salary payments to former staff will be $3.6 million. Of this, $0.2 million will be for former employees not separated through the reduction-in-force. The cost of $3.4 million will pay severance and unemployment compensation for the approximately 130 employees involuntarily separated on September 1, 1984 in the Office of Facilities Engineering and the Regional Operations Facilities Engineering and Construction.

## TYPES OF FRAUD

Question: Please give us some examples of the kinds of fraud you are finding in:

- The Social Security Program
- Medicare/Medicaid Program
- Departmental grants and contracts.

Answer: Examples of fraud in the Social Security Program are:

- Identity Fraud - Use of false or fraudulently obtained Social Security Numbers (SSN) to defraud Federal, State, and local benefit programs. We have also found that many individuals are assuming the identity of beneficiaries.
- Misuse of Records and Information - Employee corruption involving conspiracies to sell or improperly use confidential information from SSA records and systems.
- Employee SSN Fraud - Employee corruption involving sale of SSNs.
- Systems Manipulation - Manipulation of computer systems which fraudulently establish or divert benefits.
- Individual Benefit Fraud - False representations to obtain benefits by filing claims for non-existent persons and failing to report changes impacting on benefit eligibility. The number of convictions obtained from such fraudulent uses was 634 in FY 1983.
- Disability Fraud - Our primary concentration at this point has been in large scale multi-subject schemes to falsify medical certifications in disability cases.

The following examples pertain to the Medicare/Medicaid Program:

- Billing for patients not requiring ambulance transportation and representing on billing that patients could not sit, stand or walk and were non-ambulatory, or billing for patients who did require ambulance services but who were basically provided taxi services.
- Billing for more expensive x-rays when less expensive x-ray services were performed. X-ray machines used may not have had capacity to produce type of x-rays billed.
- Billing for cataract eyeglasses for patients never receiving cataract surgery.
- Double billing for medical services rendered.
- Billing for intravenous feeding for patients in nursing homes when feeding was not performed or was more limited in nature.
- Kickbacks in the pharmaceutical industry.

- False data on cost reports.

Fraud in Departmental Grants and Contracts involves:

- Embezzlement - By either the grantee itself or employees in nearly every instance, but these cases are infrequent and usually involve relatively small amounts of funds.

INVESTIGATIVE AND AUDIT TECHNIQUES

Question: I understand that the increase in the efficiency of your operation is due in large part to modernization of your investigative techniques and by the more efficient use of computers.

What new investigative and audit techniques are used to control fraud and abuse?

Answer: As you know HHS/OIG has long been a leader in use of advanced computer audit/investigative techniques to combat fraud and abuse. The Committee is being provided a copy of documents which fully describe these techniques (Vols. I-II-III). Following are examples of just a few of the increasingly sophisticated techniques we are putting into practice:

- Project Clean Data is a refinement of a computerized application that we use often. This OIG-developed computer process detects the use of Social Security numbers (SSNs) never issued or falsely used. The SSN is a key element in determining a person's eligibility for Government benefits, such as AFDC. Past efforts to validate an SSN have only been partially successful because of the need to tie into SSA's monthly index of SSNs issued. What we've done is develop a comprehensive program that bypasses those limitations. With it we are able to spot SSNs not yet issued, those issued before the person applying for assistance was born, or those issued prior to a recipient's coming of work age. This project has been ongoing for about a year and has had a phenomenal success rate--as evidenced by the now almost 100 Governmental agencies requesting use of our program.

- We have recently developed a streamlined screening technique to identify pharmacists that issue generics but charge Medicaid brand name prices. What makes this screen unique is its close to 100 percent "hit" rate accuracy. No longer do auditors and investigators have to search through several feet of computer printout for improper charges of this type--our program does it for them.

- As a variation on an older theme, we are now looking not only for excessive individual use of controlled drugs but excessive family use as well. Medicaid limits the number of prescription drugs an individual is entitled to during a year. A means of bypassing this control is having prescriptions issued to different members of a family. We developed a computer application that identifies such excessive use by a family. This application was successfully run in one State and is now being expanded to others.

- Our use of portable microcomputers in the field has been a success story in itself. In just the last quarter over 130 applications were run. Savings in terms of staff time were $217,000; recoveries, $706,000; costs questioned, $4.5 million; and potential value of all other findings was over $50 million!

These are examples of what we are doing now. Let me describe what is in store for the future.

- We're currently perfecting a multi-purpose computerized regression/correlation analysis for establishing relationships between data. This would enable OIG staff to survey a program area quickly and to pinpoint potential problems. For example, in university situations such a program would identify those overhead costs whose increases drive others disproportionately high.

- We are currently designing a computer program to detect persons or institutions using fictitious information (such as aliases, differing addresses, and other schemes to avoid detection) to receive more Government benefits than they are entitled to. The computer process involves:

    - First, sequencing the computer records so that all records for the same "real person" will be as close together as possible. We are working on several techniques in this area. They include (1) grouping like-sounding names; (2) standardizing addresses so that the same address "looks" the same to the computer--regardless of how it may be spelled; and (3) recognizing cases of entirely different names and addresses, but where other personal data point to the computer records as belonging to one person.

    - Secondly, using probability theory to compare the records and to pinpoint specific cases where it is highly likely that the computer information is fictitious.

- SSA mainframes have been used to identify and target specific suspects and suspect activities. Records containing characteristics showing a high propensity towards fraud are identified by traditional investigative techniques, and computer matches and screens are used to isolate these records for further investigation.

- The AFDC States Benefit Project utilizes a minicomputer to track the status of specific requests, to identify problems in processing, and to track results of cases emerging from the project.

- SSA electronically produces a biannual listing of addresses to which 10 or more newly issued Social Security cards are mailed in a six-month period. Our Office of Investigation (OI) field offices obtain investigative leads from these listings.

- Microcomputers are being used in the field to gather investigative data, sort it, and, in some instances, share the data with other agencies.

- A microcomputer in the Chicago region contains data from Project SSNAPBACK. SSN cards confiscated from known deportable aliens are forwarded with accompanying INS arrest reports to the Chicago OI Office. The computer sorts and arrays data retrieved from the cards and reports. The State of Illinois has used the data to identify SSN's improperly used to obtain unemployment benefits. Total projected savings since 10/83 are in excess of $182,088. This project will soon be expanded nationwide.

- Boston's microcomputer calculated individual and projected annual savings for over 500 cases within a few hours. Without the computer the job would have taken a week.

- The Boston region is putting a package together on the microcomputer to identify valid SSN's assigned to ineligible persons. They plan to send the information gathered to the other agencies as an assist in identifying false claims. They also intend this as a source of information for SSA's records annotation processes.

- Boston is also establishing an investigative leads program. SSA district offices in New England constantly send in information concerning potential fraudulent activities but the allegations usually are not sufficient by themselves to open investigations. By putting this information on the microcomputer, the field office expects to relate enough separately reported allegations to support active investigations.

## INTRA-DEPARTMENT WASTE, ABUSE AND FRAUD

Question: How has your office impacted on intra-department waste, abuse and fraud?

Can you supply us with some examples.

Answer: The Office of Inspector General reviews on a cyclical basis various internal control procedures used by Departmental Operating Divisions for cash management, debt collection, procurement, personnel/payroll, processing grant/contract administration. Examples of specific reviews follow:

- Grant/Contract Administration - A recent audit disclosed that one State charged the cost of social services to the Aid to Families with Dependent Children Foster Care Program when such costs are specifically excluded from Federal reimbursement. These charges totaling $34.5 million, should have been charged to another Federal program subject to a ceiling which the State had already exceeded. We recommended a financial adjustment of $34.5 million.

- Cash Management - Auditors surveyed each of the six HHS cash advancing systems and found that internal controls were generally adequate, except that cash drawdowns were not always timely recorded at the Departmental Federal Assistance

Financing System (DFAFS) at least partially due to delay in receiving payment vouchers from Treasury. (This process is being replaced by Treasury's Financial Communication System.) In addition, auditors found: (1) interest costs of about $21 million were incurred annually because grantees drew down excess Federal funds under the letter of credit and Treasury check payment methods in advance of their immediate needs; (2) cash balances reflected on recipient's expenditure reports were not always accurate; (3) funds were advanced to recipients without identification of the specific awards for which the cash drawdown related; (4) recording of cash drawdowns under one of the letter of credit systems was not always made timely which resulted in reduced control over cash balances; and (5) substantial amounts may be lost annually due to delays in closing out grants.

o Procurement - PHS' National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) awarded three contracts totaling $1.2 million for the development of a comprehensive program information system referred to as "PINS." In-house costs of $800,000 were also incurred.

After seven and a half years and a cost of $2 million, the project was abandoned without the system becoming operational. We found that the system was not successfully implemented because specifications were out of date and incomplete; efforts to obtain technical advice were not documented; deliverables were not adequately reviewed; the development plan was not followed; and computer resources were inadequate.

Our recommendations called for PHS to take action to prevent such occurrences in other system developments. (In FY 1984, PHS plans to spend $8 to $10 million on development of such systems.) The Deputy Assistant Secretary for Health Operations generally agreed with our findings and recommendations and advised us that corrective actions were being taken.

o Debt Collection - On a cyclical basis, the IG monitors the Department's debt collection activities. For this period we examined various Public Health Service (PHS) debt collection activities/procedures. We also assessed action taken by PHS in resolving prior problems in reporting debts in accordance with OMB, Treasury, and Department requirements.

Although PHS has taken a number of steps to improve debt collection activities, several problems still continue:

- Loans receivable for the Health Professional Student Loan (HPSL) and NSL programs were overstated because the Department's share of cancelled loans was not recorded ($1.6 million for HPSL and $59.5 million for NSL).

- Various errors in accounting records for both programs resulted in overstatements totaling $8.5 million.

- Health Maintenance Organizations program loans receivable (and accured interest) were overstated by $40.5 million because PHS did not adjust accounting records for write offs of amounts owed by closed HMOs.

PHS has developed a plan--approved by OMB--for improving debt collection activities which should correct these problems.

o Personnel Management - The Office of Personnel Management (OPM) has statutory responsibility for administration of Employee Benefit Programs. These programs--Civil Service Retirement, the Federal Employees' Health Benefit Program, and the Federal Employees Group Life Insurance Program--are contributory benefit programs funded by employee and Government contributions. Certain administrative functions are delegated to agency personnel and payroll offices. These responsibilities include determination of employee eligibility for program coverage, collection and remittance of premiums and retirement deductions to OPM, the maintenance of records, and submission of reports.

Auditors found the Department was generally administering various personnel management payroll/accounting functions properly. However, information reported to OPM was not always current because in certain cases payroll deductions were reported late, resulting in an annual loss in interest income to the Civil Service Retirement fund of about $90,000. Also, certain employee separation actions were not always accurate or timely processed.

The Department agreed to take action on recommendations made to correct these weaknesses.

## STATE MEDICAID FRAUD CONTROL UNITS

Question: We have had several reports about changes in the administration of the Medicaid Fraud Control Units.

Please explain to the Subcommittee your plans for these units.

Answer: There will be no change in the administration of the program. The only change for this program is with the location of the dollars to support these entitlement grants to States. The functions of the State units are soley related to Medicaid and should be reflected with all other Medicaid costs of the Department. Therefore, the dollars to support these grants will henceforth be included in the Medicaid budget of the Health Care Financing Administration which has responsibility for the Department's Medicaid and Medicare Expenditures. However, the costs associated with their oversight, certification, review, etc. will continue unchanged and unaffected as part of the OIG budget and responsibilities.

## TRANSFER OF CHILD SUPPORT ENFORCEMENT AUDIT FUNCTIONS

Question: Why have you chosen to transfer the Office of Child Support Enforcement Audit Function to the OIG?

Answer: The proposal to transfer the Office of Child Support Enforcement (OCSE) Audit Division and its functional responsibilities under Title IX-D to OIG was made to centralize responsibility for all Departmental audits within OIG. Such a transfer would enhance the independence of OCSE audits to meet Governmental auditing standards and better coordinate HHS' single audit responsibilities under OMB Circular Number A-102, Attachment P. Additionally, we have audit staff in over 45 field offices while OCSE is located in only 13 geographic sites. This greater number of OIG geographic sites will provide greater flexibility in providing audit coverage.

## EARLY ALERT SYSTEM

Question: What is the early alert memo system and how does it operate?

Answer: As a preventive tool, when program weaknesses or vulnerabilities are encountered that give rise to opportunities for fraud or abuse, Fraud Alerts are issued. Depending upon the nature of the systemic weakness these alerts may be directed to program managers for correction of the defect and/or for devising a means to detect potential wrongdoers. The alert may also be used to place our in-house staff of investigators, inspectors and auditors on look out for similar modus operandi for developing better screening techniques, follow-up audits and reviews. Each major OIG activity - audit, investigations, and inspections - have operational early alert systems.

All OIG alerts are brief but concise to assure readability and recognition. The distribution of all alerts is based on the nature of the vulnerability identified.

## GRADE LEVELS FOR INVESTIGATORS

Question: I understand that beginning investigators in the OIG are hired at a GS-5 level and earn approximately $18,000.

Does this low entry level hamper your efforts to recruit qualified investigators?

How much training do you provide these beginning investigators?

Can they be effective against the highly sophisticated administrative attorneys and accountants that are hired by the private sector?

What GS level would be necessary to attract experienced investigators?

Answer: In the first half of FY 1983, the Office of Investigations attempted several recruitment actions for GS-1811-5 Criminal Investigators in various cities around the country. For the most part these actions were unsuccessful as they failed to attract qualified candidates. Most of these vacancies were reannounced at the GS-7 and GS-9 levels. These reannouncements were more successful, particularly at the GS-9 level.

All beginning Criminal Investigators are sent to the Criminal Investigators School at the Federal Law Enforcement Training Center as soon after their appointment as possible. Upon completion of the Criminal Investigator training, beginning investigators are also sent to the Center's White Collar Crime Seminar. In addition, newly appointed investigators attend regional and national training courses provided by OIG and outside professional law enforcement agencies and professional groups. All these activities are designed to strengthen the individual's investigative skills and knowledge of the Department's programs.

An apprentice investigator, working alone, would not be very effective against experienced adversaries. However, all beginning investigators are closely supervised, and are assigned to work with experienced senior investigators. Formal education, training, direct supervision, as well as on-the-job experiences and counselling allows these individuals to develop their own skills and abilities and become effective against sophisticated defrauders.

Generally an "experienced" investigator able to work an investigation with little or no supervision would be a GS-12. However, if you mean what grade level would have to be offered to acquire the skills of an individual who would rapidly develop into an effective investigator; we believe a GS-9 level is appropriate.

## OFFICE OF THE SECRETARY REORGANIZATION

Question: As you have just heard, we are concerned about the extensive reorganization within the Office of the Secretary.

What effect will these changes occurring in the Office of the Secretary have on the I.G.?

Do you anticipate any organizational changes in the O.I.G.?

Answer: The Office of Inspector General will not be directly impacted by the staff reductions occurring in the Office of the Secretary. These reductions and/or streamlining of operations will result in the Secretary relying even more on the work of OIG for oversight functions. However, any such additional duties are not viewed as a burden and would not adversely impact on the IG operations.

We have no plans at this time for organizational changes within OIG.

## COUNTERFEIT SOCIAL SECURITY CARDS

Question: What can you tell us about your investigation into counterfeit Social Security Cards?

How many Federal dollars are being lost due to this problem?

Do you have any information on how this money is being used by the "counterfeiters"?

Answer: Counterfeit Social Security Number (SSN) cards are used in criminal schemes involving fraudulent identities and usually are only one facet of a large packet of false identification documents used in such schemes. These schemes may be used to have such diverse effects as shielding illegal aliens; aiding fugitives from justice; furthering other illegal activities such as check and credit card fraud or even furthering terrorists or espionage activities.

In order to detect and deal effectively with counterfeit Social Security cards, we have developed a number of special projects designed to further define the scope of the SSN fraud problem. For example, Project Clean Data detects the use of SSNs never issued or falsely used. Another recently initiated nationwide project is called "SSNAPBACK" to identify sources of counterfeit SSN cards or improperly obtained valid SSN cards. Seized Social Security cards and copies of arrest reports from INS are forwarded to the closest Office of Investigation (OI) regional office. The OI regional office will extract and send selected data to State agencies within the State of arrest (and to OIG headquarters for creation of a master tape which will be sent to all 50 States on a routine basis) to be run against State benefit program rolls.

Other benefits from the project would be to identify and target sources of false documents and to identify corrupt SSA employees who provide illicit documents to the illegal alien community. We expect this feature of the project to have great deterrent value.

Projected savings are expected to be in excess of $25 million a year.

We are continuing to direct a substantial amount of effort to the false identification problem of which the Social Security card is a part. We are attempting, with joint efforts from other law enforcement agencies, to investigate large scale schemes and individual cases to combat this type of fraud.

On September 23, 1982, the Commissioner of Social Security, testified before the Permanent Subcommittee on Investigations of the Committee on Government Affairs, United States Senate, that "The fact is that there is no estimate of the costs of misuse of the Social Security card and number. We do now, however, know from the cases that have been investigated, that the Social Security card and number do often contribute to perpetration of fraud schemes using fraudulent identity. Usually, the SSN card is only one of a whole packet of identification documents used in such schemes..."

An estimated $24 billion per year is lost through fraud involving false identification. Since the SSN is used as the key in identification systems throughout all levels of economic and financial transactions in the United States ranging from local, State and Federal benefit programs to local, State and Federal tax systems, to private and Government sponsored financial institutions, the counterfeiting or falsely obtaining of SSNs is involved in the vast majority of this fraud.

There is no available data on how this money is being used by the "counterfeiters."

## OIG COST EFFECTIVENESS

Question: You have indicated on page 99 in your budget justification an increase in the cost effectiveness ratio of your fraud and abuse activities from 4:1 in FY 81 to 22:1 in FY 84.

How do you measure this ratio and what does it demonstrate?

How well are you really doing in your quest to eliminate fraud, waste and abuse?

If Congress were to give you a blank check for this function, how would you use it?

Answer: The ratio demonstrates the dollar returned and saved (benefit) for the government vs. the OIG dollar cost to achieve that end. Thus in FY 1984, we are projecting a $22 benefit for each OIG dollar in cost.

We are doing a good job in our quest to eliminate fraud, waste and abuse. Although there are no indications by any study within or outside the Government suggesting a significant increase in fraud in the Department's programs between FY 1981 and FY 1983, our statistical results have increased substantially during this period. Administrative sanctions of wrongdoers are up over 300% since 1981, convictions have increased over 700% and dollar savings have increased over 800%.

## OIG RESOURCE LEVEL VS. ACCOMPLISHMENTS

Question: Again looking at the chart on page 99, your Department has increased its activity and results in the area of Fraud and Abuse control since you have become Inspector General.

How have you been able to achieve these successes without significant increases in employee strength?

Could you accomplish more with more resources?

Do you have a workload backlog?

Do you have any unresolved audits?

Answer: You are correct. We have significantly increased our accomplishments in the past two years. To achieve this the Office of Inspector General has focused on two major objectives (1) shifting OIG priorities to give priority to the high dollar/high risk programs of the Department and (2) improving OIG management practices to maximize efficiency and effectiveness of operations. The successful pursuit of these two objectives has increased OIG statistical results to the Federal Treasury and expanded OIG productivity.

The availability of additional resources would positively affect accomplishments. However, I have not requested additional resources and will not until I am confident that the existing resources are operating at a maximized level of productivity. So long as our productivity is improving at such a great rate, it is difficult to determine how much more productivity could be achieved by additional resources.

The Office of Inspector General does not have a backlog, but we are faced with a never ending workload. We have eliminated the backlog problem by better management of the work performed and the establishment of priorities for activities to be undertaken.

Over the last four years, the Department has made record strides in resolving final audit reports. Prior to my appointment as Inspector General in 1979 there were 1,241 unresolved audits with monetary findings of $135 million and in FY 1980 there were 666 unresolved audits with monetary findings of $38.5 million. As of September 30, 1983, the number of unresolved audits over six months old was one.

Regarding the significant internal management reports where recommendations have not been implemented or the Operating Divisions are moving too slowly in implementation, these matters are routinely reported to Congress. Some of the most important areas are:

- Second Surgical Opinions
- Medicare Round Down
- Housekeeping Services
- Psychiatric Services
- More Frequent FICA Deposits Needed
- Cancelled Checks
- Duplicate Shelter Allowance

A complete description of these audits and recommendations is contained in the OIG Semiannual Report which has been provided to the Congress.

## OIG RECOMMENDATIONS

Question: I understand that your office issues recommendations to units of the Department of Health and Human Services based on investigations and audits.

How are these recommendations received?

What are you doing to assure that these recommendations are implemented?

Are those that are not implemented in a reasonable time brought to the attention of Congress?

Please provide this Committee a list of all unimplemented recommendations.

Answer: We have been extremely successful in obtaining full cooperation from Department program officials in the conduct of audits, investigations and inspections. The methodologies we use reinforce this level of cooperation. From the initial undertaking of a project, Department managers are advised of: the start-up of all major assignments, their purpose, scope, and key target dates for completion. Any significant finding is immediately written-up and sent to the appropriate official. An exit conference is held to brief managers on the findings. An opportunity is provided for report, and managers to comment on the draft report, and, notification is given prior to the release of the official report. The only exception to this process is for some investigations for which security may pose problems.

By using this methodology, the program managers are not surprised by the findings which result in a positive receiption and frequently prompt implementation.

In those instances in which program managers delay in the implementation of findings or refuse to accept, we inform the Congress.

We are currently in the final stage of preparing the OIG Semi-annual Report for the period October 1983 thru March 1984. This report provides the status of our recommendations. This report will be provided the Committee and other members of Congress immediately upon completion

## LEGAL AUTHORITIES FOR INVESTIGATORS

Question: Do your investigators have adequate legal authority to perform their jobs?

What additional authority would be necessary to make them more effective?

Answer: The OIG at HHS is statutorily responsible for investigating fraud and abuse in HHS programs and operations. This includes sole responsibility for enforcing twenty-two criminal statutes concerning those programs. The law enforcement authorities currently exercised by OIG criminal investigators--among them, authority to issue subpoenas, administer oaths, conduct undercover operations and engage in consensual monitoring--have enable those investigators to achieve considerable success in investigating and referring for successful criminal prosecution cases of individuals attempting to defraud the Department. However, our efforts could be enhanced by the grant of additional law enforcement authorities.

Although the IG subpoena documents, a subpoena is often ineffective. For example, records may be altered or destroyed during the time alloted for compliance. Recognizing this, the Attorney General has authorized the IG to request search warrants under Rule 41(a) of the Federal Rules of Criminal Procedures. Pursuant to that rule (and 18 U.S.C. 3105), OIG criminal investigators may also serve search warrants. However, the Department of Justice prefers that OIG not execute search warrants because OIG investigators are not empowered to make arrests (in the event of confrontation) or to protect the premises by use of firearms. Therefore, we must rely on the assistance of other law enforcement agencies whenever an investigation requires a search or arrest. This has presented several problems. First, those agencies are reluctant to devote time and resources to investigations which are unrealted to their substantive responsibilities. Indeed, certain "traditional" law enforcement agencies (such as the Secret Service) are statutorily prohibited from exercising their law enforcement powers on matters without their jurisdiction. As a result, HHS often relies on United States Marshals, who are not trained investigators. Second, each agency is burdened with its own caseload and often fails, understandably, to give priority to HHS matters, resulting in delays in OIG investigations. Finally, officers of other law enforcement agencies, though expert in their respective fields, are unfamiliar with technical HHS fraud issues, and as a result, may overlook critical evidence.

Therefore, legislation which would clarify the authority of criminal investigators in OIG/HHS to execute search warrants, and would authorize such agents to make arrests and carry firearms would greatly increase our ability to perform effectively our law enforcement responsibilities.

[Note: The views stated above are those of the current HHS Inspector General. The Administration has not submitted a legislative proposal to expand the law enforcement authorities of HHS investigators. The Office of Management and Budget is currently considering the views of the HHS Inspector General, among comments solicited throughout the Federal law enforcement community, in an examination of procedures for legislative development involving Federal criminal law enforcement authorities. Pending completion of this examination, the views expressed above do not necessarily represent those of the Department or the Administration.]

## PROSPECTIVE REIMBURSEMENT PROGRAMS

Question: Have you been observing the Prospective Reimbursement programs and will your office become involved in analyzing this new program?

Answer: My office has been examining various aspects of the Medicare prospective payment system (PPS). We started with front-end reviews of HCFA's proposed implementating regulations to assure that needed controls were in place from the system's start. We are now analyzing each element of the current operating program to determine cost effectiveness and pinpoint weaknesses. With an eye to the future, we are looking now at capital costs (interest and depreciation) to see that inflation costs are not incorporated into the payment system. Following are examples of a few of our efforts:

o To evaluate the impact of PPS, we are developing an information base of approximately 200 hospitals. The following questions will be addressed: Has PPS been effective in curbing the rate of increases in total hospital costs and Medicare payments? Does the assignment of costs to DRGs under PPS properly reflect reasonable payments? And finally, what provisions of PPS legislation contribute to fraud, waste or abuse with the program?

o We are looking to computers to help in our analysis of PPS. One use is to test the many computer software packages currently being marketed to hospitals claiming to maximize a hospital's reimbursement under PPS. By running test data through these packages we will be able to determine if they contain abusive or fraudulent procedures.

- We are looking at capital costs from a variety of perspectives, such as the impact on Medicare of: sale and resale of medical facilities; computation of Medicare's share of gains from sales; depreciation paid by Medicare on Federally-financed facilities; and continuation of return on equity capital or reimbursement costs.

Already we have identified a number of ways inflated capital costs are being passed on to Medicare. On March 21, 1984, I testified on our findings before two Subcommittees of the House Ways and Means Committee. Pending the inclusion of capital costs in PPS, I suggested that a moratorium be imposed to prevent Medicare participation in the increased costs of assets resulting from sales ($750 million over 5 years according to the Congressional Budget Office).

## CIVIL MONEY PENALTY PROGRAM

Question: Please explain the Civil Money Penalty Program and list some of its accomplishments.

Answer: Prior to the passage of the Civil Monetary Penalties Law (CMPL), there simply was no effective sanction against many cases of Medicare and Medicaid fraud.

Historically, false claims that were not deemed appropriate for criminal prosecution were handled civilly under the Federal False Claims Act or under a State equivalent. Cases of potential fraud prior to passage of the CMPL were forwarded to the Department of Justice (DOJ) for prosecution. However, United States Attorneys frequently declined to accept Medicare and Medicaid cases for such reasons as, low dollar amount and lack of staff resources. With the passage of CMPL, we now have an effective deterrent against health care providers who knew or had reason to know that they were submitting false or improper claims.

The OIG signed a Memorandum of Understanding (MOU) with the DOJ which provides that DOJ review all cases being pursued under CMPL to insure that DOJ does not want to pursue them under the False Claims Act (FCA). Once the OIG has completed its investigations, secured DOJ review and found settlement of the false claims inappropriate, the Department of HHS, Office of General Counsel (OGC), can then conduct an administrative hearing before a Departmental Administrative Law Judge (ALJ). A decision of the ALJ can be appealed to the Secretary. Judicial review of penalties and assessments is by a United States Court of Appeals.

A more detailed explanation is contained in an article from the Notre Dame Law Journal which has been provided to the Committee.

In the relatively short time that the CMPL program has been in existence, we have achieved successes in several areas. With assistance and cooperation from the DOJ, the OIG has implemented a MOU specifying procedures for handling CMPL casework which could serve as a model for the entire Federal Government, if Government-wide legislation similar to our CMPL is enacted.

Staff in the CMPL area have devoted considerable time to conducting extensive training of the requirements of the new law.

We have also established close lines of communication with Assistant United States Attorneys (AUSAs) in the development of the civil aspects of Medicare and Medicaid fraud cases. Manuals developed by CMPL staff serve as the primary source materials for field investigators, both Federal and State, as well as, intermediaries who provide Medicare reimbursements and prosecutors, both Federal and State.

Thus, in the early stages of implementation of the CMPL, resources were used for educating and training field and related staff in the requirements of the CMPL. Since initial implementation, increasing numbers of cases are beginning to flow to us for processing.

Thus far (through March 1984), implementation of the CMPL has resulted in $2.9 million in actual settlements by providers. One case alone resulted in a settlement of almost $1 million to the Department. Additionally, the investigation and processing of cases under CMPL has resulted in $273,000 in projected savings to the Government.

Nine cases are currently being readied for the administrative hearing procedure. Well over three quarters of a million additional dollars is expected to be awarded to the Department from the administrative hearings currently being processed.

## Office for Civil Rights

### DECLINING WORKLOAD

Question: Your budget justification indicates a decline of 549 complaints: a 32 percent reduction over 1981 levels. Why are complaints declining?

Answer: We can't be certain about the reasons for the trend, but several factors may be behind it. For example, discriminatory treatment today is often subtle and complex and difficult to isolate from other factors, such as socio-economic status, that may contribute to lack of access to health care and social services. In addition, many of our beneficiaries aren't aware of their legal rights, and many recipients of Department funds are not aware of their compliance responsibilities. OCR's voluntary compliance and outreach activities are designed to broaden awareness of civil rights standards, and we hope this will bridge the gap.

### STAFF REDUCTION

Question: You also indicate that you expect to receive the same number of complaints in FY 85 -- yet you are requesting a reduction of almost $1.1 million in budget authority and staffing reductions of 50 positions. Please explain your rationale and identify in what functions you will take the 50 position reduction.

Answer: The proposed budget reduction is based on two main factors: the decrease in the complaint workload since FY 1981, and the increased efficiency in processing complaints. While complaint receipts have dropped during the last few years, until now OCR's authorized positions have not been reduced commensurate with the decline in the complaint workload. With the reduction of 50 positions, OCR will be able to commit sufficient resources to legally mandated reviews and other non-complaint activities because of the declining complaint workload. The FY 1985 budget provides 32 more positions for compliance activities (other than complaints) than were available in FY 1981. Although we estimate that complaint receipts will fall by 32 percent between FY 1981 - FY 1985, the loss of 50 positions represents only a 10 percent staff reduction.

OCR will absorb the position reduction proportionately in all program areas. OCR intends to reduce the number of positions allocated to complaint investigations and pre-grant reviews by 20 positions. The number of positions assigned to post-grant reviews and monitoring will be reduced by 17 positions. Five positions will be reduced from voluntary compliance and outreach. And we expect to reduce program management by 8 positions.

## GRACE COMMISSION

Question: How has the Office for Civil Rights reacted to the Grace Commission report?

Answer: The Grace Commission recommended a reduction of 169 full-time positions for OCR because it concluded that we could achieve greater productivity and efficiency in administering the enforcement program. OCR is continuing to improve productivity and efficiency. Although our budget request includes a position reduction, it is considerably less than that proposed by the Commission. In addition, the Commission suggested some organizational changes which we believe would be inappropriate, such as merging OCR into the Department's Office of General Counsel.

## DISCRIMINATION AGAINST THE HANDICAPPED

Question: I understand that about one-third of your workload is concerned with discrimination against the handicapped. What kind of complaints are you getting in the area covered by Section 504?

Answer: Under Section 504, 36 percent of the complaints are employment-related; 15 percent allege differential treatment within programs; 14 percent concern admissions policies and practices; and 12 percent deal with accessibility or availability of services. The remaining Section 504 complaints involve multiple allegations and a variety of other issues.

Question: How much time is necessary to process these complaints?

Answer: The time to completely process an uninvestigated Section 504 complaint has averaged 48 calendar days while the processing of an investigated complaint has averaged 327 calendar days.

Question: How many cases were turned over to the Department of Justice in FY 1983?

Answer: During FY 1983, OCR forwarded one Section 504 case to the Department of Justice.

BABY DOE COMPLAINTS

Question: How many Baby Doe complaints have you received?

Answer: Between May 18, 1982 (when the Department first notified hospitals that Section 504 applied to discrimination against handicapped infants) and April 1984, OCR received 62 complaints or reports alleging discrimination.

Question: How many have you investigated?

Answer: There have been 30 on-site investigations.

Question: Please describe how you handle a Baby Doe complaint.

Answer: After a complaint has been received, it is immediately given to the Infant Doe Coordinator.

1. The Infant Doe Coordinator verifies jurisdiction (receipt of Federal financial assistance) and notifies the Director, OCR, other appropriate headquarters staff, and the regional manager having jurisdiction where the complaint originated.

2. The regional manager contacts the recipient (usually the hospital administrator) and assigns the case to an investigator.

3. The regional manager and investigator conduct a conference call with the Director and pertinent headquarters staff to decide the investigative process.

4. The investigative process is implemented and conference calls are conducted between headquarters and regional officials throughout each phase of the investigation until the decision is made that the investigation is complete.

Question: How do you protect the rights of the parents in the handling of a Baby Doe complaint?

Answer: Since our enforcement is restricted to recipients of Federal funds, we have no jurisdiction over parental decisions. We are simply trying to enforce Section 504, which requires that recipients of Federal funds--in these cases, hospitals and child protective services agencies--not discriminate on the basis of handicap. As explained in our regulation, it is the responsibility of State agencies to review parental decisions. Our role is to see that State agencies are applying their own State laws in a nondiscriminatory manner.

## LEGAL SERVICES

Question: What is the effect of the loss of 15 positions in FY 1984 for legal services? Is this reduction hampering your ability to process civil rights complaints?

Answer: The Committee requested OCR to submit a report by January 1, 1985 indicating the effects of this position reduction in legal services. We are monitoring the workload of the attorney staff to assess the impact and we will submit the report by next January 1. At the present time, the position reduction has not delayed or otherwise hampered our ability to obtain needed legal assistance in a timely fashion.

## RENT AND COMMUNICATIONS COSTS

Question: It would seem to follow that if you are going to reduce your staff, you should also reduce your office space. Why are you requesting an additional $182,000 for rent and communications?

Answer: The FY 1985 budget request reflects a reduction of $197,000 in space rental costs from the FY 1984 amount, due to the personnel staffing reduction. However, an additional $222,000 for space rental charges and $57,000 in other communications costs offset this reduction, resulting in a net increase of $182,000.

## RAND HEALTH INSURANCE EXPERIMENT

Question: I understand that you are continuing to support the Rand Health Insurance Experiment. Please describe the experiment, its accomplishments to date, any anticipated accomplishments, and finally: How do you expect this long-term experiment to impact upon the Department's policy-making?

Answer: The Rand Health Insurance Experiment is a study in which 2,700 families have been randomly assigned to health insurance plans with differing coinsurance rates and maximum out-of-pocket expenditure limits. The objectives of the study are to measure the effects of patient cost-sharing on the demand for medical care, the quality of care received, and the health status of participants. The study also examines the relationship between cost-sharing and specific types of services (e.g., preventive services). And finally, the experiment is a significant contribution to basic research on the demand for, and efficacy of, health care. It provides a unique data base for further analysis and makes several contributions to research methodology.

Among the more significant findings to date are:

- Persons fully covered for medical services spend about 50 percent more than those with only an income-related catastrophic plan.
- Full coverage leads to greater use of ambulatory care and a higher hospital admissions rate.

- Most patients admitted to the hospital exceed the catastrophic expenditure limit and therefore receive free care at the margin. As a result, hospital expenditures per admission do not differ significantly between the experimental plans.

- Cost-sharing affects adults' expenditures more than those for children.

- Dental, mental, and optical service utilization are all substantially influenced by patient cost-sharing.

- Utilization of health care is much lower for participants in an HMO than for those with complete coverage under a fee-for-service plan.

- For the average participant, as well as for subgroups differing in income and initial health status, no significant effects were detected on eight measures of health status and health habits.

Further analyses planned for completion during FY 1984 include: comparison of HMO utilization with conventional plans; effect of multiphasic screening on utilization; use of telephone calls as substitutes for office visits; demand for prescription drugs; and demand for dental care and the quality of care. Analyses planned for FY 1985 include: utilization of maternal and prenatal care; cost and quality of care by type of provider; use of preventive care during the first year of life; outpatient care in the HMO; and a description of baseline insurance coverage.

The Health Insurance Experiment has had a profound impact on the making of policy in the Department. The study provides unique and invaluable information about consumer behavior under different health care financing plans. The information is especially important to the Department as it considers alternative strategies to bring about a reduction in the inflation of health expenditures. Recent legislative proposals place considerable emphasis on consumer choice of insurance plan and competition as methods of holding down costs. Most of the results are directly applicable to the debate over such proposals. Information on the distribution of expenditures and the response of health care utilization to cost-sharing have been used for cost estimation of various health care proposals under consideration by the Congress.

Data and analysis from the study will also aid in the evaluation of the quality of care received by the poor and minorities, of health manpower policies, and of preventive care. Perception of health status, satisfaction with care received, and choice of provider are also being investigated. Such research will contribute to an understanding of how consumer choice plans might operate. This study is the only one to assign individuals randomly to an HMO; consequently, it will provide unique evidence on a major dispute with respect to competition proposals, that is, whether HMOs achieve their savings by discrimination against poor health risks.

## LONG-TERM CARE

Question: Your budget request shows continued expenditures for research on long-term care? What are you doing in this area?

Answer: Our role in long-term care (LTC) research is one of gap-filling, coordination, and leadership. A number of HHS agencies (e.g., HCFA, AoA, NIH) have operational or research responsibilities related to LTC. Because the issues involved cut across these agencies, ASPE has been designated to take the lead on policy development and research related to preventing unnecessary institutionalization.

ASPE has several research and demonstration projects underway. They include research on case management, the supply of LTC services, private financing, State incentives for noninstitutional care, and detailed information on the dependent elderly who are cared for at home. Major projects include the following:

The Channeling Demonstration. Our major effort is the design and evaluation of the Channeling program, conducted jointly with AoA and HCFA. The objective is to test the feasibility and cost-effectiveness of an alternative community-based service delivery concept, integrating health and community services. The demonstration provides coordinated health and social services to individuals 65 and older who are unable to manage the essential activities of daily living on their own and who lack informal supports. The demonstration seeks to assess the effects of case management (with and without additional financial resources) on the ability to live in less restrictive settings; the public and private costs of care; the quality of life and mortality rates; and the burden of care on families and other informal caregivers. It also seeks to measure the cost effectiveness of Channeling and to examine the effects on different subgroups. The demonstration is in the third year of operation.

The National LTC Survey and the Survey of Informal Caregivers. These are complementary surveys. One surveys a national sample of over-65, dependent elderly who are living at home. The other surveys a sample of the informal (unpaid) caregivers who are providing care to them. Analysis of the data gathered will be done inhouse and a public use tape prepared. This data is critical to assessment of the impact of changes in the LTC system. Little or no information has been available on the dependent elderly who are being cared for in the home.

Private Financing of LTC. This study will provide a comprehensive description of LTC financing by private individuals, pension funds, and insurors. It will also describe the barriers to expansion of private financing and suggest some new possibilities for removing the barriers and encouraging private financing of a larger share of LTC expenditures.

Supply of LTC Services. Past attempts to model the supply of LTC services, especially nursing home beds, have not been successful, because the attempts have not taken account of State control of licenses and certificates of need which vitiate the effect of market forces. This study will provide a full description of the State regulatory approaches, as input to later attempts to model those processes to permit projection of the supply of nursing home beds and other LTC services.

State Incentives and Programs to Encourage the Care of Dependent Elderly at Home. Several States have recently enacted laws providing tax incentives to relatives to care for dependent elderly at home, and others have incentives and programs to encourage such care. This study will describe those State laws and programs and assess their effectiveness.

## HEALTH AND SOCIAL SERVICES

Question: I understand that your office conducts a great deal of work to identify private sector approaches to the financing and management of health and social services. How has your work impacted upon Secretarial decision-making in these areas? Please provide for the record a description of the work you have done in this area over the past five years.

Answer: Research on private sector approaches to financing and managing health services has been instrumental in identifying methods that warrant consideration in Secretarial decision-making. The Department's goal is to develop policies that complement private sector cost management strategies and reduce unnecessary regulatory burdens. Private sector experience with alternative delivery systems has lead to support for policies that offer Medicare beneficiaries a choice between traditional coverage and HMOs or other competitive medical plans. Research indicates that purchasers and consumers can benefit from market approaches and incentives-based health care cost strategies. Recent studies also provide technical information on major attributes and pitfalls of alternative strategies. For example:

- Adverse selection is found to be the most serious problem of multiple health plan choice. Large plans such as the California Public Employees Retirement System have managed to survive this problem, but not without difficulty. Accurate actuarial adjustments and other approaches to the risk selection problem are of primary importance.

- Studies conducted with HCFA have revealed substantial variation in case severity in some diagnosis related groups (DRGs), laying the groundwork for improvements in DRGs and for extention of the DRG concept to currently uncovered areas of reimbursement (e.g., MDs and long-term care).

- There has been extensive corporate experimentation designed to reduce the rate of growth of private health expenditures. Many corporations have recently instituted benefits redesign, private utilization review, worksite wellness programs, and inhouse corporate medical programs.

- A study of the uninsured has confirmed that the majority of the uninsured are employed, but the number of uninsured workers grew over the late 1970s. Further research will investigate options for reducing the size of the uninsured population.

Most of the private sector research in the social services area is still in progress and therefore has had little chance to impact on departmental decisions. One study which has been completed looks at the use of voucher programs in day care and other public services. The study results have generated a great deal of interest in ways to increase the choice of those who need social services while reducing administrative costs of those who provide them. Other work in the social services area, now underway, includes: a demonstration of the feasibility of employer support for locating day care; a description and assessment of one local model of respite care; and an examination of methods of involving families in the care of the developmentally disabled.

The following are detailed descriptions of the private sector studies in the health services area.

Evaluation of Competitive Incentives on Employees' Choices of Health Care Coverage. The purpose of this study was to analyze private sector initiatives for health care cost containment, specifically, current benefit programs of employers. Analyses addressed the following questions:

- To what extent do competitive incentives result in employees choosing lower cost plans with higher cost-sharing?

- Do multiple choice plans generate economies in health care consumption?

- Do employers who include competitive features tend to have lower premium inflation over time than those who do not?

- Do some competitive features appear to be more effective in inducing economies than others?

Analysis of Adverse Selection in Private Sector Health Plan Choice. This study addresses one of the most frequently voiced criticisms of multiple choice proposals -- that some plans will be driven out of business because of selection bias associated with high-cost users rather than because of efficiency gains by their competitors. Using data from two firms, the study will examine whether persons who switch plans have the same average utilization in the period before the change as after the change and whether their utilization equals the utilization of nonchangers. Particular attention will be paid to plan switching that appears related to pregnancy and elective surgery.

Analysis of Plan Choice in the California Public Employees Health Benefits System. This project identifies and evaluates factors associated with choice of health plans under the California multiple choice health benefits system. The analysis includes an examination of factors relating to plan selection and contrasts findings with evidence on the Federal Employees Health Benefits Plan. The study is based on cross-sectional data on enrollees, plans, and geographic areas in California. Information obtained from the study will be useful in determining enrollee behavior in multiple choice health plan situations.

Analysis of Compensated Multiple Choice of Health Plans. This study was designed to determine the feasibility of conducting a large-scale demonstration of private sector health plan choices involving payment of rebates to employees who select low-cost plans and simulating tax-free status of these rebates. The project generated information on potential participating firms, experimental design and data collection issues, and projected demonstration costs.

Private Sector Health Care Initiatives. This project was designed to yield information on private sector initiatives that are being undertaken by purchasers and providers of health care, the forces that promote or impede initiatives, and what is known about their impact on the health care market.

- The Synthesis Report focused on what is known about various types of private sevctor initiatives -- plan design, alternative delivery systems (HMOs and preferred provider organizations), private utilization review, health care coalitions, worksite wellness programs, new activities of corporate medical departments, and cost containment activities of hospital trustees.

- The case studies in four communities (Boston, Denver, San Diego, and Iowa) offer a community-wide perspective on the market characteristics that influence the direction and scope of private sector activity, by both providers and purchasers.

- A statistical analysis, using secondary data sources, seeks to explain why some communities have high levels of selected initiatives, notably prepaid health plans, private utilization review, and health care coalitions.

Employer-Sponsored Benefits. The purpose of this project is to provide data on employer-provided health insurance and especially on the amounts paid for insurance by employers and employees. The data file provides representative statistics on employer payments to employee health plans and on the benefit structure of such plans.

University/Industry Relationships. This is a detailed, systematic study of the phenomenon of university/industry relationships (UIRs) in the life sciences. Surveys will be conducted and case studies developed to examine potential benefits and dangers of these relationships. Despite the potential importance of life science UIRs, relatively little is known about the actual nature, extent, and consequences of these relationships. Developing such information will assist university, industry, and government decisionmakers to formulate policies that maximize the benefits and minimize the risks of UIRs.

Study of Industry-Based Health Promotion and Disease Prevention Programs. This project is designed to evaluate the effectiveness and efficiency associated with corporate-sponsored health enhancement programs over a four-year period. Programs in three firms will be studied. Selected topics and an evaluation monograph aimed at the corporate audience are among the expected products.

Evaluation of Prudent Buyer Packages. The primary purpose of this project is to assess and evaluate efforts in the private sector to inform and encourage employees to "buy prudently" when purchasing health services and products. A survey of employers will be conducted to determine what kinds of consumer information is being developed, the effectiveness of the efforts, and the extent of use in the private sector.

Actuarial Analysis. The purpose of this project is to obtain the services of a team of specialists that provide the skills needed to assemble actuarial cost models and estimates. The study will update national projections for expenditures in the years 1984 through 1994 for the health care services covered under employer provided private insurance as well as by the Medicare and Medicaid programs.

Health Insurance Experiment. This is a large scale, multi-year experiment in which more than 2,700 families at six different sites were assigned to insurance plans with different levels of cost-sharing or to an HMO. Families were enrolled for either three or five years and exhaustive information was collected on utilization of health care, health status, satisfaction with care, employment, family income and related data.

This year's effort is directed to data base reconciliation and the creation of public use files. Analytic work using claims, Health Report, questionnaire and screening exam data, and building on considerable methodological work in earlier periods, is scheduled to continue throughout FY 1984.

Study of Preferred Provider Organizations. This study will be designed (FY 1984 award) to examine operational PPOs and examine the emerging structures and their capacity to serve as cost-effective alternative financing and delivery system models. The project will specifically:

- obtain first-hand insights into the implementation process -- problems and operational issues related to developing PPOs;
- examine data relevant to addressing important research questions such as -- who uses PPOs and under what circumstances, business/corporate initiatives designed to channel employees to the PPO, and benefits design features which serve to complement or enhance the market attractiveness of PPOs;
- assess the cost-management potential of PPOs -- by focusing the analysis on the key characteristics of PPOs (e.g., methods and criteria for selecting and monitoring providers, presence and characteristics of the utilization review system); and
- compare the populations that select HMOs in contrast to those attracted to PPOs (e.g., ascertain what plan design characteristics influence employee choice).

Analysis of Medical and Hospital Utilization Review in the Private Sector. This project will be the major FY 1985 policy research project in the private sector initiatives series. Anecdotal evidence from past studies and reports indicates that many firms, particularly those which self-insure and are committed to cost containment, have instituted stringent forms of UR that have not been evidenced to any great degree in public or voluntary programs. These UR programs tend to be data-intensive and often use third party administrations to review claims and implement both prospective and retrospective review. Because they are privately organized by payers, they are not required to adhere to externally imposed constraints.

The study would determine: how prevalent and quickly growing is the practice of firm-sponsored private UR; what are the commonalities and differences between existing programs; how do such programs develop and utilize provider-specific data; what sanctions are imposed on noncomplying providers: and what magnitude of cost savings are achieved? The study would acquire nationwide data on this phenomenon with more detailed data from selected operational programs.

## RESEARCH STUDIES

Question: Of the research studies that have been supported by your office, which do you consider most significant and what have you learned? Historically, please describe how your division of Policy Research has affected the long-range policy of the Department?

Answer: Work has proceeded during the past two years on a number of significant projects, including:

Research on Welfare Dynamics. Preliminary work has found that most poor individuals do not remain poor for very long. Research shows that almost half the women who begin a spell of AFDC receipt leave the program within two years; however, women who received welfare for at least two years are quite likely to be long-term recipients. The finding that most poverty is temporary alleviates the need for massive intervention. On the other hand, it also suggests that targeted assistance to the persistently poor may be effective.

Retirement Income and the Economy. This is a program of data collection, behavioral research, and policy analysis on the retirement process and the well-being of older individuals. Research indicates that the proportion of the elderly in poverty, roughly twice that of the general population in 1966, had fallen to approximately the same level by 1981 and Social Security has a smaller effect on early retirement than had previously been estimated.

Health Insurance Experiment. This is a study of more than 2,700 families randomly assigned to insurance plans with differing out-of-pocket expenditures to measure the effects of cost-sharing on the demand and quality of medical care. The study has shown that cost-sharing for medical services reduces utilization substantially without adversely affecting health.

Findings from these research activities have made important contributions to the development of HHS policies and legislation. Health policy studies, for example, have contributed directly to the development of the President's Health Incentives Reform legislation sent to the Congress last year, which included proposals to provide volunteer vouchers under Medicare and for catastrophic coverage under that program.

Much of the data, cost estimating capability, and computer support used by the Department in developing and assessing new proposals is supported by this appropriation. Over the years, we have developed a number of data sets and models, such as: a simulation model of the retirement system which projects the demographic and economic characteristics of a sample of the population 75 years into the future; an immigration model; a health financing model; and a long-term care supply and demand model. These data and models allow comprehensive and refined analysis of policy options and facilitate rapid and accurate response to Congressional inquiries. Examples of the recent uses of this information include the following:

- The immigration model has been used to make estimates of the impact of the Simpson-Mazzoli immigration legislation.
- The various AFDC and Medicaid models have been used to estimate costs and savings of the Child Support Enforcement program legislative proposals under consideration in the Congress. We currently are assessing how best to collect additional child support data.
- The cost and impact estimations for policy changes in the AFDC program were done using these models. We recently provided detailed estimates of the impact of the Administration's proposed legislative changes to the Ways and Means Committee.
- Simulation models were used in support of the initiative to limit the amount of employer payments for health insurance which are untaxed (the "Tax Cap").
- During the deliberations of the President's Commission on Social Security, estimates were provided of the revenues that could be raised with alternative methods of taxing benefits.
- The health financing model and other survey data have been used to develop the Department's prospective payment proposal, and in preparing our proposed legislation to tax employer-based health insurance above a specific level.

## EMPLOYMENT REDUCTIONS

Question: According to your budget request, you are planning to reduce employment in FY 1985 by almost 25 percent? Will this require any involuntary separations?

Answer: Our ceiling is 120 full-time equivalent employees by the end of FY 1985, 110 permanent employees and 10 temporary "Policy Research Associates." The FY 1985 budget justification shows 115 permanent positions, which allows for some part-time permanent employees. Currently, there are 160 people onboard in my office: permanent employees, temporary employees, and term employees. Between now and the end of FY 1985, there will be a significant reduction from this number, principally through attrition or early retirement of permanent employees, and by not renewing the employment of many of the temporary and term employees. We hope that there will be no involuntary separations.

## FY 1985 REQUEST

Question: What was your FY 1985 request to the Secretary? Please describe her reasons for the reduction from the level of your request.

Answer: The FY 1985 request for the Policy Research program of $11 million, the same as the FY 1984 President's Budget, was approved by the Secretary. The amount of the request was later reduced in part to reflect the lower amount appropriated by the Congress for FY 1984 and to reflect greater reliance on the Operating Divisions as recommended by the Grace Commission.

## CHILD SUPPORT LEGISLATION

Question: I understand that the Secretary has proposed child support legislation which has now passed the Senate Finance Committee. How have you participated in the formulation of this legislation, and what have you done to gather additional information about the problem?

Answer: The child support legislative package submitted by HHS to the Congress in July 1983 was developed by our office in conjunction with the Office of Child Support Enforcement. Our office had lead responsibility within the Department for overseeing the bill as it moved through the Congress. We provided technical assistance to the staffs of both the Ways and Means and Finance Committees by defining and analyzing variations suggested by Committee staff. In conjunction with this activity, we estimated the overall cost of the various options as well as their State-by-State impact. Census information tells us that in 1981, of the four million women owed child support payments for their most recent divorces, only 47 percent received the full amount due. This means approximately 2.12 million absent parents with obligations are not paying. It is important to develop a profile of these absent parents and to understand why they are or are not paying their child support obligations to improve collections and program administration. The best way to understand this population is to interview the absent parents themselves, yet all the information we have on absent parents is through the custodial parents.

We have just completed a feasibility study of implementing a survey of absent parents with obligations. For this study we examined child support enforcement and court records in order to determine if they are suitable as a sampling frame for a survey and to discover what data they contained. We determined from this study that these records could be used as a sampling frame, as we found we could locate absent parents.

In FY 1985 we plan to implement this survey in cooperation with the Office of Child Support Enforcement. This effort will allow us to obtain a profile of absent parents with obligations, understand why absent parents are or are not paying their obligations, and determine the effects of State administrative structures and enforcement practices on collections.

# PROSPECTIVE PAYMENT ASSESSMENT COMMISSION

## STATEMENT OF DR. STUART H. ALTMAN, CHAIRMAN

### OPENING STATEMENT

Senator WEICKER. Last we have the Prospective Payment Commission. This Commission was established by Congress as part of Public Law 98–21 which established the new medicare hospital prospective payment system.

This Commission is charged by Congress to collect and analyze all information concerning prospective payment and to report its recommendations to both the Secretary of Health and Human Services and to the Congress.

It would appear that the work of the Commission could be a critical factor to the success of the prospective payment system.

The recently chosen Chairman of the Commission, Dr. Stuart H. Altman, will testify. Welcome, Dr. Altman. Please introduce your staff and proceed.

Mr. ALTMAN. Good morning, Mr. Chairman. My name is Stuart Altman and I am the Chairman of the newly established Commission.

### PREPARED STATEMENT

Senator WEICKER. Your statement in its entirety will be included in the record.

[The statement follows:]

## STATEMENT OF STUART H. ALTMAN

Good morning Mr. Chairman, and Members of the Committee. My name is Stuart H. Altman, Ph.D., and I am Chairman of the newly established Prospective Payment Assessment Commission (ProPAC). Joining me this afternoon is Donald A. Young, M.D., the Executive Director of the Commission.

The Commission was established by the Congress at the time the new Medicare hospital prospective payment system was enacted in April, 1983 (Public Law 98-21, the Social Security Amendments of 1983).

The 15 members of the Commission were appointed by the Director of the Office of Technology Assessment (OTA) in mid-November, 1983. The Commissioners are individuals from a wide variety of public and private sector organizations representative of key segments of the health care financing and delivery system in this country. I have included for the record brief biographical sketches of the Commissioners.

The Commission has twice met as a body and thanks to the excellent staff assistance provided us by OTA, we are well along in establishing ourselves as a working unit. In addition to selecting an outstanding Executive Director, we are in the process of selecting key staff, we have adopted operating by-laws and procedures, and we are drafting a working policy statement. We have entered into an agreement with the General Services Administration (GSA) for them to provide us with the necessary personnel, payroll, accounting and physical plant support services.

In creating this first full year budget of the Commission, we have been guided by the requirements placed on the Commission by the Congress and by an assessment of how other Congressional and Executive Branch units with similar mandates operate. Congress charged the Commission with critical responsibilities for oversight, consultation and recommendations which will ensure that the Medicare hospital payment system is appropriately adjusted to maintain the continued viability of this new way of paying hospitals for services furnished to Medicare beneficiaries.

Since its beginning in 1965, Medicare had paid for inpatient hospital care on a retrospective, cost-based system. This system contributed greatly to the tremendous increase in hospital costs and Medicare expenditures over the past 17 years by paying, after the fact, for whatever costs were incurred by a hospital in caring for Medicare patients. There were no incentives built into this system to encourage hospital management and physicians to seek the most cost-effective methods of care. The major goal of prospective payment is to reverse these past incentives through a system which rewards efficiency by allowing hospitals to make a profit when their costs fall below the prospective payment amount. Similarly, however, the hospital will have to absorb a loss when their costs exceed the prospective payment amount.

The prospective payment system mandated by the Congress is being phased in over a three-year period. The system uses a new tool, diagnosis related groups (DRGs), to measure the kinds of resources needed to treat patients who have a particular diagnosis, and to set a rate which Medicare will pay the hospital for a patient in each DRG category. In order to assure that the system is kept up to date, the DRG classification and relative payment levels will need to be reviewed and appropriate changes made periodically to reflect new forms of treatment and patient care that have been shown to be medically efficacious. It is in this area that much of the work of the Commission will focus.

The law also charges us to collect and assess all relevant information on the appropriate percentage changes necessary to update the payment amounts for each hospital discharge, and to report our recommendations to the Secretary of the Department of Health and Human Services and the Congress. In developing its recommendations, the Commission is to study changes in the hospital "marketbasket" (the cost of items used in caring for hospital patients), changes in hospital productivity, technological and scientific advances, quality of care, and the utilization of costly, though effective, methods of care. This information is to be developed to ensure that the prospective payment system will continue to provide the proper incentives for hospitals to offer cost-effective care. The Commission's work, I believe, is critical to the success of the new hospital prospective payment system and to the greater goal of maintaining high quality patient care for Medicare beneficiaries while containing the ever-growing cost of the Medicare program.

The Commission is required to make recommendations to the Secretary of DHSS and report its findings to the Congress by April 1st each year. As we begin our work, we are aware of the difficult and important tasks that face us. While our first priority is the reports due in less than one year, we must also begin the work necessary for a longer range analysis of the very significant changes that are occurring in hospitals and in the delivery of health services generally, in part due to the new incentives inherent in prospective payment.

We have tried in this budget to balance the mandates of the law with an assessment of what other governmental agencies and private organizations are doing to collect and analyze needed information. Before submitting this budget on behalf of the Commission, I discussed it with the Office of Research and Demonstrations of the Health Care Financing Administration, the health programs of the Office of Technology Assessment, the Congressional Budget Office and the Office of the Assistant Secretaries of Health and of Planning and Evaluation, HHS. My goal was to determine what they were planning to do to implement and monitor the prospective payment system and where the Commission could profitably supplement their efforts. In addition, this budget has been reviewed by staff of the Office of the General Services Administration (GSA) and we have a letter from GSA, which I will insert for the record, indicating that our proposed figures are appropriate and in line with comparable commissions and related agencies.

Our requested total budget for the year beginning October 1984 (FY 85) is for $3,131,774. While this might appear to be a sizeable increase over the $1.5 million appropriated for this year, this Committee and the House Appropriations Committee clearly recognized that our current appropriation was for less than a full year's operation and for a year in which it is unlikely that we would be able to mount any significant outside data collection or technology assessment activities. I understand that the Administration's 1985 budget contains funding at the current level of $1.5 million for the

Commission. The Administration, however, included this amount before the Commission had held its first meeting and without the opportunity to consult me or other members of the Commission or our staff on what an appropriate full year budget should be in order to carry out the mandates of the Congress.

For the most part, the items in the budget are straightforward and flow from the provision in the prospective payment legislation (P.L. 98-21) which allows the Commission to employ up to 25 personnel, to provide transportation, subsistence and compensation to the 15 Commissioners and to enter into contracts or make other arrangements as may be necessary for the conduct of the work of the Commission. Three items do, however, require a separate discussion.

Under Rent and Communications (Section 23), the Commission is requesting $100,000 to purchase 10 word processors and analytic micro-computers. Before this request was made, I reviewed the operations of OTA, CBO and ASPE in the Department. I also looked into the operations of my own school which is a $7.0 million social policy research and training institution. Each of the units have gone, or are hoping to go, to full automation for their secretarial support and analytical staffs. All can point to demonstrable savings in personnel and expensive main frame computer time. Our plan is to move in a similar way.

The two remaining items requiring separate discussion are the $100,000 for technical consultants (Section 11.3) and the $1.0 million for data collection and technology assessment contracts (Section 25). In seeking these funds, the Commission recognized the importance of the extremely complicated and detailed responsibilities given to it by the Congress. It was also mindful that it was being asked to make recommendations which would not only significantly influence the $40 billion annual Federal Medicare hospital expenditure level, but which would also have a significant impact on $80 billion being spent by States, private insurance companies and individuals for hospital care yearly. The Congress has asked the Commission to provide the Secretary and itself with the results of research studies, analyses and assessments never previously undertaken by any group

We are taking this charge very seriously, but we know that no Commission of 15 individuals or staff of 25 could hope to possess all the expertise required, or be able to obtain on its own the information needed to carry out its responsibilities. We will need help and help which can only come from trained professionals in universities, research institutes, medical schools, hospitals and other organizations. Congress clearly recognized this need in authorizing the Commission to enter into contracts, grants and other arrangements. You can be assured that we will collect no information or conduct no study that will duplicate those carried out by another Federal or State agency or by an objective private organization. Nor are we planning to create another long term research operation. Our goals are limited to the mandates spelled out for the Commission in P.L. 98-21 and are focused on the immediate needs of the Department and the Congress with respect to the operation of the Medicare prospective payment system.

Mr. Chairman and members of the Committee, thank you for giving me this opportunity to present the first full year budget of the Prospective Payment Assessment Commission. I and my colleagues will be more than happy to answer any questions you may have.

## ESTABLISHMENT OF COMMISSION

Mr. ALTMAN. We were established under Public Law 98-21. The commissioners were appointed by the Director of the Office of Technology Assessment in late 1983. The commissioners are individuals from a wide variety of public and private sector organizations, representatives of key segments of the health care financing delivery system.

I have included for the record brief biographical sketches of the commissioners. The Commission has met twice as a body and thanks to the excellent staff assistance provided to us by OTA we are well along in establishing ourselves as a working unit.

In addition to selecting an outstanding Executive Director, we are in the process of selecting key staff. We have entered into an agreement with the General Services Administration for them to provide the necessary personnel, payroll, accounting, and physical plant support services.

In creating the first full year budget of the Commission, we have been cognizant of the requirements placed on the Commission by the Congress and by an assessment of how other congressional and executive branch units with similar mandates operate.

Since its beginning in 1965 medicaid has paid for inpatient hospital care on a retrospective cost basis. The system contributed greatly to the tremendous increase in hospital costs and medicare expenditures over the past 17 years by paying, after the fact, whatever costs were incurred by hospitals in caring for medicare patients. There were no incentives built into the system to encourage hospital management or physicians to seek the most cost-effective methods of care.

The major goal of prospective payment is to reverse these past incentives through a system which rewards efficiency by allowing hospitals to make a profit when the costs go below the prospective payment amount. Similarly, however, the hospital will have to absorb a loss when their costs exceed the prospective payment amount.

The prospective payment system mandated by the Congress is being phased in over a 3-year period. This system uses a new tool, diagnosis-related groups, to measure the kinds of resources needed to treat patients with a particular diagnosis and to set a rate which medicare will pay to the hospital for a patient in each DRG category.

In order to ensure that this system is kept up to date, the DRG classification of relative payment levels will need to be reviewed and appropriate changes made periodically to reflect new forms of treatment and patient care that have been shown to be medically efficacious. It is in this area that much of the work of the Commission will focus.

Now, I indicated in my testimony several areas we will focus on in particular in developing recommendations, both to the Department and the Congress.

We have the responsibility to impact on the annual rate of increase by examining hospital market basket which includes the cost of items used in caring for hospital patients, changes in hospital productivity, technological and scientific advances, and quality of care issues. This information is to be developed to assure that the prospective payment system will provide the proper incentives for hospitals to offer cost-effective care.

The Commission's work, I believe, is critical to the success of the new hospital prospective payment system and to the greater goal of maintaining high quality medical care for the medicare beneficiary while containing the ever-growing cost of the Medicare Program.

The Commission is required to make recommendations to the Secretary of the HSS and report its findings to Congress by April 1 of each year. As we begin our work, we are aware of the difficult and important tasks that we face.

While our first priority is the report due in less than 1 year, we must also begin the work necessary for a longer range analysis of the very significant changes that are occurring in hospitals and in the delivery of health services generally, in part due to the new incentives inherent in prospective payment.

We have tried in this budget to balance the mandate of the law with an assessment of what other governmental agencies and private organizations are doing to collect and analyze needed information.

Before submitting this budget of the Commission, I did discuss this with the Office of Research and Demonstrations in the Health Care Finance Administration, health care programs in the Office of Technology Assessment, and the Congressional Budget Office, and the Offices of the Assistant Secretaries of Health and Planning. My goal was to determine what they were planning to do to implement and monitor the prospective payment system and where the Commission could profitably supplement their efforts.

In addition, this budget has been reviewed by the staff of the office of the General Services Administration. We do have a letter from GSA which I will submit for the record.

Our request for total budget for the year, beginning October 1984 is for $3.1 million. While this might appear to be a sizeable increase over the $1.5 appropriated this year, this committee and the House Appropriations Committee clearly recognized that our current operations were for less than 1 full year, and for a year in which it was unlikely that we would be able to mount any significant added collection or technology assessment activity.

I understand that the administration's 1985 budget contains funding at the current level of $1.5 million for the Commission. The administration included this amount before the Commission had held its first meeting and without the opportunity to consult with me or other members of the Commission or staff on what appropriately the budget should be in order to carry out the mandates of the Congress.

For the most part, the items in the budget are fairly straightforward and flow from the provisions in the prospective payment legislation which allow the Commission to employ up to 25 people and to provide transportation and subsistance. There are three items, however, that do require separate discussion. Let me just mention them.

Under rent and communication the Commission is requesting $100,000 to purchase 10 word processors and analytic microcomputers. Before this request was made I reviewed the operations of OTA, CBO, and the Office of the Assistant Secretary for Planning and Evaluation in the Department. I also looked into the operations of my old school, Brandeis, which is a $7 million social policy research and training institution.

All can point to demonstrated savings in personnel and expensive mainframe computer time. Our plan is to move in a similar way.

The two remaining items requiring separate discussions are the $100,000 for technical consultants and the $1 million for data collection and technology assessment contracts. In seeking these funds, the Commission recognized the importance of the extremely complicated and detailed responsibilities given to it by the Congress.

It was also mindful that it was being asked to make recommendations which would not only significantly influence the $40 billion which is annually spent by the Federal Medicare Program, but which also has a significant effect on the $80 billion being spent by State, private insurance companies, and individuals for hospital care yearly.

The Congress has asked the Commission to provide the Secretary and itself with the results of research studies, analyses, and assessments never previously undertaken by any group. We are taking this charge very seriously, but we know that no commission of 15 individuals or staff of 25 could hope to possess all the expertise that's required or be able to obtain on its own the information needed to carry out its responsibilities.

Quite frankly, we will need help and we will need help that will only come from individuals trained and who work in universities, research institutes, medical schools, hospitals, and other organizations. Congress recognized this need in authorizing the Commission to enter into contracts, grants, and other arrangements.

You can be assured, though, that we will collect no information or conduct no study that will duplicate those carried out by other Federal or State agencies, or by an objective private organization; and this I want to emphasize, nor are we planning to create another long-term research operation.

Our goals are limited to the mandates spelled out for the Commission in Public Law 98–21 and are focused on the immediate needs of the Department and the Congress with respect to the operation of the medicare prospective payment system.

Mr. Chairman, members of the committee, thank you for giving me this opportunity to present the first full-year budget of the Prospective Payment Assessment Commission. I and my colleagues will be more than happy to answer any questions you have.

Senator WEICKER. I have several questions for response to the record, but I think the main one is: Have you had indications from the administration that they intend to go along with the budget that you've requested? Now that you've developed your budget, what's the story?

There's a certain amount of disparity between $1.5 and $3.1 million.

Mr. ALTMAN. We have not talked with them since then. It is my understanding that your committee and the Congress decides what our budget is. They don't. And that we are independent of them with respect to the budget.

I have talked to some of the staffers at OMB, but we have not talked specifically; sort of, like, "Well, put in $1.5 million and see what you can get."

Senator WEICKER. That obviously is a problem that we have to solve.

Mr. ALTMAN. As I indicated, Mr. Chairman, there was no discussion on the $1.5 million.

Senator WEICKER. I understand that.

Dr. YOUNG. The Director of the Office of Technology Assessment, a legislative branch agency, is charged by the Congress with the responsibility to appoint the Commission as well as an oversight responsibility. Since the funding for the Commission flows from the medicare trust funds, the appropriation is considered to be within the executive branch, but the Department of Health and Human Services has no other authority or responsibilities. The Commission is independent in determining its tasks, in keeping with congressional intent, and in requesting an appropriation. Further, it is subject to legislative branch, not executive branch, oversight. The executive branch had no information upon which to recommend an appropriation other than the first year start-up level of $1.5 million.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. I have further questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### Prospective Payment System

Senator Weicker: The newly instituted Prospective Payment System is an important and significant change in the way Medicare pays for hospital services.

Why is it necessary for a Commission to do ongoing studies and make recommendations for change and adjustment? Does this indicate a significant flaw in this new system?

Dr. Altman: The new system has many strengths and incentives to reverse the prior incentives to overspend. These incentives, however, also have the potential to adversely impact on the quality of care furnished Medicare beneficiaries. The Prospective Payment System, and its primary tool diagnosis related groups, was built on information developed in the late 1970s and early 1980s. The nature of medical care is continually changing and new and better information is becoming available. The system is at significant risk unless continued adjustments are made to reflect better understanding of problems which are identified and to take into account changes occurring. The Congress recognized the seriousness and importance of this responsibility by creating the Commission and requiring it to undertake the appropriate studies and assessments as a base for the recommendations it must develop.

### Advantages of Independent Commission

Senator Weicker: What are the advantages of an independent commission? Why can't the tasks you are undertaking be carried out just as well by the Health Care Financing Administration (HCFA)?

Dr. Altman: The Prospective Payment Assessment Commission (ProPAC) can bring a spirit of openness and independence to the analysis and evaluation of the complex issues related to hospital care. The Commission and its staff have as their only task the development of recommendations related to maintaining the fiscal constraints and integrity of the system while promoting quality care. We have the freedom to consult widely with interested groups and individuals and to engage in an open and healthy debate on the best approaches to solve problems. HCFA's research orientation is on specific policy studies, many requested by the Congress, and it must carry out its work within the budget, competing funds and other constraints of the Department of Health and Human Services. Some areas are likely to be of sufficient importance that independent assessment and evaluation from two perspectives, HCFA and the Commission, will be of great value in developing difficult recommendations and decisions.

### Budget

Senator Weicker: As indicated in your testimony, the Administration has requested $1.5 million for FY 1985. You are presenting a budget that would require an appropriation of $3.1 million.

Please explain, in detail, why there is such a large difference between the two requests.

Dr. Altman: We have presented our best estimate of a budget for the first full year of operation. Our current appropriation of $1.5 million was for less than a full year of operation and for a year in which it was unlikely we could mount a significant research effort.

The Administration requested the same $1.5 million for our second year before the Commission was appointed and before our first meeting. As a result, we had no opportunity to discuss our needs and plans with them. An appropriation of $1.5 million for FY 1985 would not allow us to staff up anywhere near our authorized level of 25 or to fund the very important assessments and evaluations necessary to maintain the integrity of the prospective payment system. It is likely we will not expend our full $1.5 million appropriation for FY 1984 and therefore will carry funds over to FY 1985. We will provide committee staff with our best estimates as we get closer to mark-up.

## Research

Senator Weicker: You are asking for $1 million for research and policy analyses and assessments. I recognize that these tasks are a major part of your function.

Why so much in the first full year?

What do you expect to learn from these activities and how do you expect the results to be used?

Dr. Altman: The Commission is required by statute in making its recommendations to consider the hospital marketbasket (the cost of items used in caring for hospital patients), hospital productivity, technological and scientific advances, quality of care and long-term cost-effectiveness of services. In order to carry out its responsibility to identify medically appropriate patterns of health resource use, the Commission is required to collect and assess information on regional variations in medical practice, length of hospitalization and the safety, efficacy and cost-effectiveness of new and existing medical and surgical procedures, practices, services and technologies. This is a very complex set of issues and many of the areas have not previously been examined in depth. It will be necessary in many cases to develop the analytic tools in parallel with the analyses and evaluations. Considering the complexity and importance of the issues and the potential impact of our findings on Medicare hospital expenditures which are approximately $40 billion, a million dollars is a very small amount. The findings from our work should be directly relevant to the development of recommendations for appropriate adjustments in hospital payments

## Commission's Role

Senator Weicker: I understand that your role is purely advisory. What impact do you expect to have on the Health Care Financing Administration (HCFA), Congress and the health care field?

What happens if the Secretary does not listen to your advice? Are there other avenues you will be able to use to make your advice known?

Dr. Altman: Although the Commission's work is advisory, it must be considered by the Secretary and will be reported to the Congress. Therefore, its recommendations and the background findings leading to the recommendations are likely to have a significant impact. Further, the Commission provides an opportunity for wide public input and discussion concerning issues of great importance to Medicare beneficiaries, hospitals, physicians, industry and many other groups.

The assessments and analyses the Commission is undertaking are not being done by any other groups and will go a long way to providing rational and sound information of great importance to Medicare beneficiaries. The information we develop and the recommendations that result will be made available to the Congress and all other interested groups as well as to the Secretary for their use.

### Budget

Senator Weicker: If this Committee agreed with the President's request and appropriated $1.5 million, how would your work be affected?

Would you be able to comply with the requirement that you provide your first set of recommendations by April 1, 1985?

Dr. Altman: We would be able to provide some analysis and recommendations by April 1, 1985. But many analyses and assessments would not be undertaken. Further, we would not be able to undertake the studies now that will provide the input to reports due in 1986 and 1987. As I indicated previously, the Commission is assigned a very complex set of issues to consider and an appropriation of $1.5 million would not allow us to consider many of the issues.

### Types of Work

Senator Weicker: Can you give us an example of the types of work you will be doing and how this work would be important to the functioning of the prospective payment system?

Dr. Altman: As an example, a new procedure which is relatively costly but greatly improves the quality of care comes along. We would like to provide the proper financial incentives to hospitals to adopt the procedure, but we would also like to provide the incentives to reduce or eliminate other services which are not necessary. Therefore, we would design a study using computer modeling, simulation or decision analysis techniques to forecast the economic impact of the new costly procedure as well as the impact on the quality of care. In doing so, we might have to consult with professionals in medical care, hospitals, industry, etc. While the staff could do some of the work, our research and policy analysis budget might be necessary for the computer simulation and decision analyis work. It is possible that such studies could show that the costly procedure actually substitutes for other more costly procedures and we could use the results to save the medical program money where the initial impression might have been opposite. As a result of our studies and the HHS Secretary's adjustments, money is saved and quality is improved.

### Financial Incentives

Senator Weicker: Under the prospective payment system, there are financial incentives that could adversely impact the quality of patient care.

Is it possible for the Commission to develop recommendations that would control hospital expenditures while encouraging quality health care:

Dr. Altman: Yes, the example I just gave illustrates how new advances can control expenditures while improving quality. In addition, our research and policy analytic studies will focus on changes in the patterns of hospital resource use such as staffing as well as scientific and technological advances and issues related to quality of care. For example, a new type of diagnostic study or surgical procedure may be gaining acceptance and its impact on hospital costs and quality of care must be evaluated in order to make the proper adjustments in specific DRGs or the percentage change factor. Such studies will provide the basis for ensuring that care is cost-effective and the new procedures replace existing ones rather than add-on as was true with the prior reimbursement mechanism.

### DRGs

Senator Weicker: I understand that two of your responsibilities are "updating" and recalibration of the Diagnosis Related Groups.

Can you explain what these terms mean and why they are important?

Dr. Altman: Updating means changing the amount of payment for hospital discharges beginning on or after October 1, 1985. Under TEFRA and for the first two years of prospective payment, Congress sets the update factor related to changes in the general hospital rate of inflation. After October 1, 1985, the Secretary of HHS is to set this rate after consideration of recommendations from the Prospective Payment Assessment Commission. In making its recommendation, the Commission is to consider general hospital rate of inflation, productivity, technological and scientific advances, quality of care and long-term and cost-effectiveness.

Recalibration is the process of adjusting individual DRG categories and prices to reflect changes in treatment patterns, technology and other factors which may change the relative use of hospital resources.

Both of these activities are very important to maintaining the integrity of the prospective payment system and to assure cost-effectiveness of hospital care while promoting high quality care.

## QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

### Representation

Senator Proxmire: Dr. Altman, some concern has been expressed over the fact that your Commission apparently does not include a representative of a major non-medical private sector employer. Since private business and industry are significantly affected by Federal health policy decisions as major purchases of health care, shouldn't they be represented on the Commission?

Dr. Altman: The authority to appoint Commissioners resides with the Director of the Office of Technology Assessment (OTA). It is my understanding that the present 15 Commissioners were selected from a large number of nominees representing many different sectors of the health field and that it was not possible to include a representative from every sector. Several members of the Commission do come from large business organizations in the medical field. I am sure the

Director of OTA will consider the additional areas such as those you mentioned in deciding on the appointment of future Commissioners.

Review of Recommendations

Senator Proxmire: Dr. Altman, the Inspector General of the Department of Health and Human Services has issued a number of reports suggesting ways in which health care costs could be reduced. For example, the Inspector General has recommended a change in the way interns and residents are paid under Medicare, proposed a mandatory second surgical opinion program, and suggested the implementation of a standard lab fee schedule.

Does the Commission intend to review these kinds of recommendations, many of which could be implemented without a change in the law, and assess their usefulness in reducing the rate of Medicare cost growth?

Dr. Altman: The Commission will undertake as its first priority the two areas required by statute, recommending annually to the Secretary the appropriate annual percentage change in payment for hospital inpatient discharges and consulting with and recommending to the Secretary needed changes in the DRG classification and relative weighting factors. In undertaking these tasks, we will look at patterns of health resource use which could include some of the areas you indicate. We will also monitor Executive and Legislative Branch actions in regard to such areas as medical education costs, payments to physicians and services furnished outside the hospital setting. Our focus, however, will be on payment to hospitals for inpatient services.

## SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until Wednesday, April 11 at 9 a.m., when we will meet here to begin our public witness hearings.

To begin with we will hear from two Members of Congress, Senator Paul Trible and Representative Vic Fazio. Following their testimony, we'll hear from public witnesses concerning the Department of Labor, the Department of Health and Human Services, and the Centers for Disease Control. Thank you very much.

[Whereupon, at 10:37 a.m., Tuesday, April 10, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, April 11.]

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